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In The

Supreme Court of the United States

LINDA A. ANDE, CHARLES ANDE, AND C.E.A., THEIR MINOR CHILD,

Petitioners,

v.

NORMAN C. FOST, PHILIP M. FARRELL, ELAINE H. MISCHLER AND ANITA LAXOVA,

Respondents.

On Petition For Writ Of Certiorari To The Supreme Court Of Wisconsin

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. ARE GOVERNMENT RESEARCHERS WHO SUBJECT BABIES IN A BLINDED CONTROL GROUP OF A RESEARCH STUDY TO MALNUTRITION AND INCREASED SEVERITY OF DISEASE BY DENYING THE BABIES KNOWN, BENEFICIAL MEDICAL TREATMENT, ENTITLED TO QUALIFIED IMMUNITY BECAUSE THE WITHHOLDING OF MEDICAL TREATMENT, WHILE HARMFUL TO THE CHILD, WAS NOT AN INVASIVE PROCEDURE?

2. WHETHER THE LONG LINE OF SUPREME COURT DECISIONS RECOGNIZING THE UNCONSTITUTIONALITY OF SUBJECTING AN INDIVIDUAL TO A HUMAN RESEARCH STUDY WITHOUT INFORMED CONSENT GAVE FAIR WARNING TO GOVERNMENT MEDICAL RESEARCHERS THAT AN INDIVIDUAL'S INFORMED CONSENT WAS REQUIRED PRIOR TO PARTICIPATION IN ANY STUDY HAVING AN EFFECT ON THE INDIVIDUAL'S BODILY INTEGRITY EVEN THOUGH THE STUDY DID NOT INCLUDE INVASIVE MEDICAL TREATMENT?

3. WHETHER THE LONG LINE OF SUPREME COURT DECISIONS RECOGNIZING THE UNCONSTITUTIONALITY OF SUBJECTING AN INDIVIDUAL TO A HUMAN RESEARCH STUDY WITHOUT INFORMED CONSENT GAVE FAIR WARNING TO GOVERNMENT MEDICAL RESEARCHERS THAT THEY HAD A CONSTITUTIONAL DUTY TO REVEAL INFORMATION TO THE CONTROL SUBJECTS ONCE IT BECAME CLEAR TO THE MEDICAL RESEARCHERS THAT WITHHOLDING TREATMENT WAS INFLICTING HARM AND DISEASE?

QUESTIONS PRESENTED FOR REVIEW – Continued

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5. WHETHER QUALIFIED IMMUNITY PROTECTS RESEARCHERS FROM LIABILITY WHEN THEY FAIL TO PROVIDE KNOWN MATERIAL INFORMATION TO ADULTS THAT IS ESSENTIAL TO THEIR DECISIONS REGARDING PROCREATION AND CONTRACEPTION?

PARTIES TO THE PROCEEDING

The Petitioners in this Court, Linda A. Ande, Charles Ande, and their minor child, C.E.A., are individuals who were plaintiffs in the circuit court, appellants in the Wisconsin Court of Appeals, and petitioners in the Wisconsin Supreme Court.

The Respondents are Norman C. Fost, Philip M. Farrell, Elaine H. Mischler, Anita Laxova, individuals. The Respondents were defendants in the circuit court, appellees in the Wisconsin Court of Appeals, and respondents in the Wisconsin Supreme Court.

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PETITION FOR WRIT OF CERTIORARI

Petitioners respectfully pray that a Writ of Certiorari issue to review the decision of the Wisconsin Court of Appeals, in *Ande v. Rock*, 2002 WI App. 136, 647 N.W.2d 265, which was given binding effect in the State of Wisconsin by the decision of the Wisconsin Supreme Court to deny review on July 26, 2002.

OPINION BELOW

The opinion of the State of Wisconsin Court of Appeals ("appellate court") dated May 16, 2002, is reported at *Ande v. Rock*, 2002 WI App. 136, 647 N.W.2d 265. The State of Wisconsin Circuit Court for Dane County ("trial court") issued an unreported decision dated January 11, 2001, granting respondent's motion for summary judgment on the basis of qualified immunity. A motion for reconsideration was filed with the trial court and denied by a decision dated April 6, 2001.

BASIS FOR JURISDICTION IN THIS COURT

This Court has jurisdiction pursuant to 28 U.S.C. § 1257(a).

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

The Fourteenth Amendment to the Constitution of the United States of America provides in relevant part: " . . . nor shall any State deprive any person of life, liberty, or property, without due process of law . . . ."

The statute at issue, 42 U.S.C. § 1983, provides, in relevant part, as follows:

> "Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State . . . subjects, or causes to be subjected, any citizen of the United States . . . to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law . . . ."

The federal regulation at issue, 45 C.F.R. § 46.116(b), provides in relevant part, as follows:

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject . . . (5) A statement that significant new findings developed during the course of research which may relate to the subject's willingness to continue participation will be provided to the subject.

STATEMENT OF THE CASE

Petitioner C.E.A., born 7-13-93, is one of an unfortunate group of about 20 children who tested strongly positive for cystic fibrosis (CF) at birth, and was unknowingly chosen to be a human guinea pig in a state run human research project, commenced in 1985, that intentionally withheld standard medical treatment for cystic fibrosis from babies in order to study the benefits of standard early treatment from birth. C.E.A., the daughter of Charles and Linda Ande, suffered from the devastating effects of CF, which include malnourishment, dehydration, and decreased lung function, while her counterparts in the study received appropriate and unquestionably beneficial care. The researchers in charge of this study had proclaimed in publication at least twice during the two years before C.E.A. was born that six years of their data had already shown early treatment of CF clearly prevented

malnourishment and decreased the severity of other aspects of the disease. Still, neither her parents, nor her treating physician were told of C.E.A.'s positive CF test, until she was eventually diagnosed on 6-26-95 due to increasing symptoms of the disease two weeks short of her second birthday. In the interim, Linda Ande had become pregnant with another child who also has CF, consistent with the genetic link in the disease.

The trial court and the Wisconsin Court of Appeals held that qualified immunity protected the state researchers' conduct because C.E.A. was not subjected to invasive treatment, and there are no cases on point demonstrating a constitutional violation for simply withholding medical treatment. These holdings allow the purposeful malnourishment and dehydration of children as long as nothing affirmative or invasive is done, and regardless of whether their parents are told about the test results or about their participation in the research project.

In 1985, medical researchers at the UW commenced a study to test a simple hypothesis: Is early diagnosis and treatment of cystic fibrosis beneficial? The answer to this question is at the foundation for similar neonatal screening for other genetic disorders.

In 1985, blood test screening and treatment of babies for other genetic disorders was statutorily mandated and carried out on all babies by the Wisconsin State Health Laboratory. The core idea behind all screening is the ability to diagnose by blood testing a rare, serious disease and to treat it before it seriously impairs the health of the baby.

It should be clearly understood that the CF study into which C.E.A. was unknowingly placed was not testing any new drugs or therapies. Both the trial court and the

appellate court opinions imply "a nutritional plan" was made available once a child was diagnosed. It is undisputed that the only thing the researchers provided were the standard treatments for cystic fibrosis. They were simply comparing children who received those standard treatments from birth, against those who were intentionally deprived of the standard treatments.

The principle researchers were Respondents Phillip Farrell and Norman Fost. Anita Laxova and Elaine Mischler were assistant researchers on the study and co-authored articles discussed below. The study tested the blood of all children born in Wisconsin from 1985 until Spring 1994 for CF and divided them into two groups. Group one, children whose parents and doctors were told they had tested positive for CF and who then began treatment at a CF center. Group two (the control group) children were not to be contacted but instead were kept in the dark and allowed to come to diagnosis naturally. Neither the child, the parents, nor the pediatrician were directly told of the positive CF test or of the child's participation in the human research project. The two groups would then be compared over time as to growth and development.

A neonatal screening brochure given to mothers at birth made short mention of the CF study following six pages of discussion on other congenital disease testing. The researchers knew from surveys that 73% of parents had no idea their child had even been tested for CF. The brochure is undisputably the only piece of information, verbal or written, the parents ever received.

Prior to the development of this blood test, CF was typically diagnosed when a child became increasingly sick – usually by an average age of four.

If children in the blinded group had not come to diagnosis naturally by the age of four, their parents and pediatrician then were to be contacted and told the results of the CF screening which had been done at birth. At that point, additional testing would be done to confirm the diagnosis and standard treatment commenced. The two groups were to be followed over the ensuing years in an attempt to answer the question posed: Does standard early treatment, beginning at birth, benefit children with CF?

There are three categories of major health problems associated with CF: (1) lack of pancreatic enzymes causing decreased ability to absorb food and resultant malnourishment; (2) excess lung secretions and resultant decreased lung function and increase in infection (pneumonia); and (3) salt loss in sweat that can lead to severe, potentially fatal dehydration. This genetic disease also carries with it a life expectancy of approximately age 30.

Treatment has been standardized for many years and includes daily pancreatic enzyme pills, vitamin supplements and aggressive daily chest physical therapy to promote clearance of excess lung secretions to fight off infection. Antibiotics are also often necessary to treat lung infections. These treatments were denied to the babies in the control group, but were provided to the babies whose parents and treating doctors had been informed of the positive CF test.

Drs. Fost and Farrell acknowledged before the study commenced in 1985 that ethically they could not do the study if they knew they were denying these children something of known benefit. By no later than 1991, these same investigators conclusively knew that early treatment of CF was in fact clearly beneficial. Inexplicably, they

failed to tell the control group to allow these children to get the treatment they had proven to be clearly beneficial.

By 1991, the respondents told their colleagues in the professional literature that six years into the study they had already

> "concluded that *malnutrition* in CF occurs during the presymptomatic state . . . This project *clearly demonstrates*, however, that normal growth and biochemical indices of nutritional status can be achieved in the majority of infants with CF when they are diagnosed via neonatal screening and managed with appropriate dietary intervention and supplements."

("Nutritional status of infants with cystic fibrosis associated with early diagnosis and intervention" by Mary S. Marcus, Sherie A. Sondel, Phillip M. Farrell, Anita Laxova, Patrick M. Carey, Rebecca Langhough, and Elaine H. Mischler. Am J Clin Nutr 1991;54:578-85) (emphasis added).

The parents of children in the control group were not told in 1991 that the study had already clearly demonstrated this fact. Nor were Linda and Charles Ande told of this fact when their baby girl was born on July 13, 1993. Instead, C.E.A. and the other control babies continued to be malnourished, dehydrated, and sickened by infection, all while the standard, available, and effective early treatments were being knowingly withheld from them.

Once again, in 1992, Farrell extolled the benefits of early treatment in the professional literature. Therein, he informed his colleagues of the importance of nutritional status in long term survival and well-being of patients with CF. Similarly, he asserted that there was a clear association between malnutrition and deteriorating lung function. Farrell further commented in the same article

that "*there is no reason* to accept nutritional failure and/or impaired growth in any individual with CF." ("Nutritional assessment and management in cystic fibrosis: a consensus report," Bonnie W. Ramsey, Phillip M. Farrell, Paul Pencharz, and the Consensus Committee. Am J Clin Nutr 1992:55:108-16) (emphasis added).

Yet, in 1992, these same researchers not only accepted, but directed intentional nutritional failure in the control group of children despite the admitted known link between nutritional status and long term survival and well-being. Although there was purportedly "no reason" to accept this shocking malnutrition of babies which admittedly impaired their long term survival, the researchers belied their assertion, and accepted that knowing infliction of trauma in order to preserve their sacred data.

This failure to reveal the information that likely would have influenced the subjects' willingness to participate was in violation of federal regulations governing research involving human subjects. The applicable section is 45 C.F.R. § 46.116(b)(5), which reads:

> (5) A statement that significant new findings developed during the course of research which may relate to the subject's willingness to continue participation will be provided to the subject.

No such statement and no such information was ever provided to the control group in the CF study.

The researchers claim refuge under the shield of qualified immunity because of previous approvals of the study by the University of Wisconsin Institutional Review Board (IRB) and the National Institute of Health (NIH). However, it is an undisputed fact that at the time C.E.A. was born, the study was being operated without approval, and the Human Subjects Committee of the University of

Wisconsin Institutional Review Board was threatening to report this fact to the NIH.

Consistent with their writings of 1991 and 1992, in October of 1993, Farrell told the Wisconsin Department of Health and Social Services Newborn Screening Advisory Group Committee on neonatal screening that the study had "found early medical treatment of children with preclinical CF is effective in delaying the onset and progression of the disease and in reducing its severity in those affected." Further, that "children with CF for whom treatment is begun early in life will later require less costly medical care and, in particular, less inpatient hospital care."

On July 13, 1993, the Andes' first child, C.E.A., was born. She was randomly placed into the control group, was not told of her positive CF test, and was deprived of treatment for CF. The researchers, including Farrell and Fost, knew the control group, of which C.E.A. was one, was not receiving any early medical treatment because their parents and doctors had not been informed of the positive test result. They knew, based on their statements to the committee as described above, that children in the control group would likely experience earlier onset and increased severity of CF and its associated health hazards, and would likely require more medical care including more hospitalizations as they aged. In spite of this, they failed to tell the parents of these children that they had tested positive and denied them the opportunity to obtain the very medical treatment the researchers were extolling would minimize the effects of the disease. This deprivation continued unabated despite the fact that the researchers commented in the professional literature in 1994, that no

potential risks of early treatment were apparent other than an occasional false positive test.

A final fact not mentioned in the appellate opinion is that the researchers finally voted to tell the control group in the Spring of 1997. This was now six years after their first article in the professional literature stating the clear benefit of early treatment. By then, there was evidence that children in the blinded group had smaller heads. They acknowledged they could not deny good nutrition and voted to unblind the controls. Even though the vote passed, they still did not unblind the control group for an additional year. By this time, the study would have been unblinded anyway according to the original plan. That is, the last subjects were randomized in the Spring of 1994 and would have been told of the test results no later than the Spring of 1998 if they had not been diagnosed naturally pursuant to the study protocol.

While this alarming conduct continued at the direction of the respondents, Linda and Charles Ande learned on or about June 26, 1995 that C.E.A. had CF. She had been suffering for months with escalating symptoms and had been tested for many things by their pediatrician. A CF test was done in late June 1995 which resulted in C.E.A. being diagnosed naturally by her pediatrician some 23 months after birth. The Ande's second child is, unfortunately, also afflicted with CF. Linda and Charles Ande did not have the benefit of the knowledge that their first child had CF when they made the decision to have more children. The date of conception for their second child was determined to have been on or about June 7, 1995.

Fost and Farrell acknowledged the importance of genetic counseling for parents with a child with CF. It is undisputed that parents of a child with cystic fibrosis have

a one in four chance of conceiving a second child with CF. This information was not provided to Linda and Charles Ande. Of course, even if it had been, they had not been told that their first baby was CF positive prior to conceiving their second child.

Throughout the pertinent time period discussed above, there was a federal regulation in place which stated in part, "no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative." 45 C.F.R. § 46.116. The Regulation's clear purpose is to prevent ignorant human subjects from being subjected to medical research without consent. There is no dispute about the failure to obtain an informed consent that complied with the federal regulations.

It is undisputed in this case that written consent was never obtained from parents of the children in the blinded group, including Petitioners. The researchers in this case have repeatedly referred to the concept of "implied consent" which is nowhere in the federal regulations. They likely mean to argue that the study fell under the "waiver of consent" provisions of the federal regulations. However, they admittedly failed to comply with the documentation requirements necessary to meet the waiver of consent provisions, and, therefore, were not complying with those federal regulations either.

Petitioners brought an action in state court asserting, among other things, a violation of their constitutional rights. Specifically, Petitioners' complaint alleged a property right to information and violation of their liberty interests related to bodily integrity and right of privacy.

A-38. Respondents moved for summary judgment in the circuit court asserting qualified immunity. A-38.

The circuit court ruled that Petitioners "must cite more than one 'closely analogous case' establishing that the respondents have violated a clearly established constitutional right. There must be a consensus of all the relevant case law on the issue." A-40. The circuit court distinguished the numerous cases involving invasive conduct as inapplicable and found Petitioners had not met their burden, granting summary judgment in favor of Respondents' qualified immunity defense. A-44.

Petitioners filed a motion for reconsideration with the circuit court which was denied. A-25. The opinion found that while Respondents were aware of "ethical problems" with the study, their obligation to obtain a participant's informed consent in the study was limited to those participants to whom they affirmatively provided treatment. A-21-22.

Petitioners appealed the trial court decision, again raising violation of property rights and the liberty interests of bodily integrity and privacy under the Fourteenth Amendment. A-14-15. With regard to Petitioners' informed consent claims, the appellate court determined the Petitioners could "identify no harm that they suffered by not giving consent to the test in the first instance," and therefore, the court declined to address these claims. A-15-16. The appellate court then reviewed Petitioners liberty interests only as they pertained to Dr. Aronson. A-16-18. Dr. Aronson is not a respondent in this action. The appellate court affirmed the circuit court's judgment. A-19.

Petitioners filed a timely petition for review with the Wisconsin Supreme Court. Petitioners' petition for review

was denied by a July 26, 2002 order and an amended order filed by the court on July 30, 2002. A-46-49.

Petitioners now seek review of the Court of Appeals' affirmation of the circuit court decision to dismiss their federal claims.

REASONS FOR GRANTING THE WRIT

A. Whether qualified immunity protects state medical researchers from passive or non-invasive conduct is an important issue of federal law that has not been settled by this Court, but which will have broad application to current human testing issues which will inevitably continue to arise in the future.

Petitioners seek relief from this decision in order to protect the thousands upon thousands of human subjects who are part of a control group in a medical study. There is no definitive decision from this court that states it is a violation of one's liberty interest to be unwittingly subjected to physical harm during human medical testing when the harm is inflicted passively, or non-invasively. The lower courts in the case at bar have ruled that, so long as no invasive treatment is administered, qualified immunity protects the conduct of state actors who knowingly allow members of a control group to suffer injury and disease. Pandora's box has been opened, and the ramification of leaving it open stands to impact all human research conducted in the United States. If the Court seizes the opportunity to hear this case, the decision will have tremendously broad applicability.

Essentially, there is no definitive decision that protects control human subjects in a medical study who are subjected to non-invasive conduct. Although the case at

bar involves the most egregious fact pattern imaginable in such cases, because the petitioners did not consent to be a part of any study in the first place, a decision on this case would apply to all control subjects whether they consented at the outset or not.

Although in this case, C.E.A. was placed into an experiment without her knowledge or consent, denied beneficial treatment even when its efficacy was clearly proven, and suffered harm to her health as a result, the concept in need of definition from this Court is actually much broader than those circumstances and would apply to all research control subjects. Control subjects classically are the subjects who get the "sugar pill" (placebo) and the other half of the study participants get the drug that the researchers hope will cure cancer, or whatever disease is being studied. If, for example, six years after the study starts, the researchers' data clearly and convincingly shows the drug will likely cure cancer, or at least is unquestionably improving the health and survival rates as compared to those who are receiving the sugar pill, the researchers doom the controls to worse disease or death if they continue with the experiment. At a minimum, the researchers must owe the control subjects a duty to disclose the fact that it has become clear that the test drug or treatment is beneficial. Failure to provide the treatment to the controls, or at least to provide the information to the controls, may be passive or non-invasive conduct – but it is "conduct" nevertheless. It still involves the same result, that is, unnecessary and intentional injury to the person.

The key is at what point do they proclaim to have proved all or part of their original hypothesis. Such a point in time is present, potentially, in all human research even if the subjects originally provided a true informed consent.

Therefore the importance of the ruling petitioners seek cuts across all research currently ongoing and future research to come. New control subjects like C.E.A. cannot continue to be placed into the study when the principal researchers have already publicly (in professional medical literature) proclaimed their data already clearly demonstrates significant benefit. C.E.A. and others like her will be harmed. Similarly, control subjects already in the study need to be told of the proven benefit or they too will likely be harmed.

While the unlawfulness of such conduct can surely be inferred from the existing line of cases which makes it unlawful to subject humans to invasive medical experimentation without their consent, the decisions of the lower courts in this case demonstrate the desperate need for a clear decision which grants protection to non-invasive test subjects.

Unfortunately, as sometimes happens in the practice of law, a game of semantics has been started. It started when the trial court found that no clear Constitutional violation existed because C.E.A. had been subjected to passive or non-invasive conduct. If she had been injected with LSD, or purposely infected with HIV, no one would doubt for a second that a Constitutional violation occurred. Yet, since C.E.A. and others in the CF control group were only passively malnourished, dehydrated, and allowed to become susceptible to lung infection, they apparently do not gain Constitutional protection. Petitioners asserted this invasive versus non-invasive rationale was a difference without distinction, but were roundly rebuffed in that argument by the trial court:

> Every case Plaintiffs cite on the issue of informed consent deals with humans having been subjected to unwanted, but affirmative, medical

> procedures or treatments. In the court's opinion, there is a clear distinction between the cases cited by Plaintiffs and the case at bar. Here, Defendants were not subjecting study participants to an invasive procedure in the initial CF screening. Infants' blood samples were routinely taken for purposes of screening for several other congenital diseases. [A-40]

Again, in its decision denying Petitioners' motion to reconsider, the trial court stridently stated that there was a material distinction between causing injury passively versus affirmatively doing something invasive to someone:

> What was obvious to the researchers was that they would have to obtain the informed consent of the parents of any child in the experimental group to whom they wanted to provide the experimental treatment. Therein lies the "meaningless distinction," as it was characterized by Plaintiffs at page 20 of their initial brief in support of the motion to reconsider, which the court makes between subjecting human research subjects to some type of *affirmative* treatment or procedure, and not doing anything other than what has always been done, which in this case amounted to leaving them alone. [A-22]

What the trial court fails to come to terms with is the fact that the *sine qua non* of the constitutional violation is the knowing infliction of harm to a human without his or her consent. Common sense says that the mode of infliction, whether passive or affirmative, should not logically matter.

The consequences of allowing the above distinction to continue without a clear message from this Court are frightening.

Consider the possibility that one of the current AIDS drug experiments, which has been underway for 5 years, yields conclusive evidence that the drug is reversing the progression of the HIV virus. If researchers published results declaring such a discovery, but failed to inform the control/placebo group and simply allowed them to die, would there be any question as to the impropriety of such conduct?

Consider where Linda and Charles Ande would find themselves if they had knowingly committed these acts against their daughter, that is, knowingly denying her standard medical treatment causing her to be malnourished, dehydrated, and suffer impaired lung function? Either the parents would be in prison, the child would be in protective custody, or both. Why should state medical researchers be given any greater leniency?

Perhaps the next study which involves withholding a known benefit from a baby, causing it to become malnourished and dehydrated will result in the death of the baby. At what point will the distinction between invasive and non-invasive treatment cease to be meaningful? Killing is killing. Injuring is injuring. Starving is starving. All are abhorrent practices that any human with any degree of common sense, let alone a licensed medical researcher, ought to know are a violation of someone's basic human rights, including the right to bodily integrity.

In short, killing people, injuring people, starving people, taking years off of peoples' lives . . . are all acceptable practices in the field of human medical research as long as you don't inject them, drug them, cut them, hit them, or otherwise affirmatively invade their person. This will remain the case unless this Court decides to send a

clear message to the lower courts that there is no distinction. Invasive or non-invasive does not matter. The right to bodily integrity is sacred and should not be disposed of via verbal gymnastics. The ramifications of not seizing this opportunity to clearly delineate the constitutional protection applicable to control subjects in the field of human medical testing are enormous.

B. Qualified immunity was improperly granted because the lower courts' decisions conflict with this Court's decisions in *United States v. Lanier*, and *Hope v. Pelzer*.

The trial court dismissed Petitioners' federal claims on the basis of qualified immunity, holding:

> For the defense of qualified immunity to fail, the plaintiff must show a "sufficient consensus" of all relevant case law indicating that the official's conduct was unlawful. See *Landstrom v. Illinois Dept. of Children*, 892 F.2d 670, 676 (7th Cir. 1990). Plaintiff **must cite more than one closely analogous case** "decided prior to the defendants' challenged actions." See *Upton v. Thompson*, 930 F.2d 1209, 1212 (7th Cir. 1991) (quoting *Rakovich v. Wade*, 850 F.2d 1180, 1205 (7th Cir.), cert denied, 488 U.S. 968 (1988).

(emphasis added). As discussed above, the trial court also found that the medical testing cases cited by the plaintiff were not closely analogous because they all involved invasive medical conduct.

The Wisconsin Court of Appeals similarly held that the researchers' failures "cannot be said to rise to the level of a violation of a 'clearly established' right because there is no closely analogous case law which interprets [the Wisconsin statute applicable to disclosure of screening

results for infant congenital disorders] to require the disclosure of tests run before the statute and applicable administrative rules required them." After acknowledging that, "Substantive due process protects against government actors who engage in conduct that 'shocks the conscience' or conduct which interferes with rights 'implicit in the concept of ordered liberty'," the Appellate Court summarily concluded that, "The Andes have failed to identify any Wisconsin or federal case law clearly establishing such an interest. Therefore, we conclude that qualified immunity bars all their federal claims."

In requiring clearly analogous cases, and in deciding that the invasive medical procedure cases were not clearly analogous, the lower courts are at odds with this Court's decision in *United States v. Lanier*, 520 U.S. 259, 117 S.Ct. 1219 (1997). *Lanier* rejected the requirement that there be a "fundamentally similar" precedent before the law is "clearly established" enough to defeat qualified immunity. *Id.* at 1226-27. Moreover, this Court stated that it had previously found the clearly established requirement to be satisfied "despite notable factual distinctions between the precedents relied on and the cases then before the Court, so long as the prior decisions gave reasonable warning that the conduct then at issue violated constitutional rights." *Id.* at 1227.

The goal of qualified immunity is to ensure that defendants "reasonably can anticipate when their conduct may give rise to liability by attaching liability only if the contours of the right violated are sufficiently clear that a reasonable official would understand that what he is doing violates that right." *Id.* at 1227 (citations omitted). In *Lanier*, this Court soundly rejected the idea that a right

cannot be sufficiently clear unless there are closely analogous cases: "[G]eneral statements of the law are not inherently incapable of giving fair and clear warning, and in other instances a general constitutional rule already identified in the decisional law may apply with obvious clarity to the specific conduct in question, even though the very action in question has not previously been held unlawful." *Id.* at 1227 (citations omitted).

Yet, the lower courts in the case at bar have refused to give meaning to generally recognized constitutionally protected rights – the right to determine and control one's medical care; the right to bodily integrity; and the right to procreation and/or contraception. Those rights appear to apply with obvious clarity to non-invasive medical test subjects (most often known as the control group) and to human test subjects who have not been given sufficient information to enable them to give an informed consent. There does not appear to be any rational reason to say, "Those are sacred constitutional rights which cannot be violated, but if the method used to violate the rights differs semantically from methods discussed in a prior case, it is okay to violate those rights."

The lower courts' decisions are also at odds with this Court's recent decision in *Hope v. Pelzer*, 122 S.Ct. 2508 (2002). Therein, this Court reiterated the holding of *Lanier*: "Our opinion in *Lanier* thus makes it clear that officials can still be on notice that their conduct violates established law even in novel factual circumstances." 122 S.Ct. at 2516. The *Hope* Court rejected the idea that "an official action is protected by qualified immunity unless the very action in question has been held unlawful." *Id.* at 2515. Rather, the "salient question" is whether or not the unlawfulness of the conduct is apparent. *Id.* at 2515-16.

In *Hope*, the petitioners made a difference-without-distinction argument similar to that advanced by the Andes in the case at bar. Hope was handcuffed to a "hitching post" and was deprived of food, water, and bathroom breaks. *Id.* at 2512-13. The respondents sought refuge under the shield of qualified immunity essentially because that specific, particular form of punishment had not been found to be unconstitutional. *Id.* at 2516. The Supreme Court rejected that argument and found fair warning was provided by looking at the bigger picture: "The use of the hitching post as alleged by Hope unnecessarily and wantonly inflicted pain, and thus was a clear violation of the Eighth Amendment." *Id.* at 2516. "The obvious cruelty inherent in this practice should have provided respondents with some notice that their alleged conduct violated Hope's constitutional protection against cruel and unusual punishment." *Id.* at 2518.

Significantly, this Court did not rely primarily upon factually similar, or closely analogous cases. Rather, it held that the knowing infliction of unnecessary injury was obviously unconstitutional without regard to the method used to inflict injury. So it is with the case at bar. The Ande's daughter, and the other control babies, were knowingly and unnecessarily allowed to suffer malnourishment, dehydration, and increased severity of disease. Does it matter whether a child is malnourished by having needed nutritional supplements withheld, or by having food forcibly pumped from her stomach? Does it matter whether a child has phlegm and mucus injected into her lungs or whether her breathing is impaired because no one is taking it out? It should not and cannot make a difference, pursuant to this Court's reasoning in *Hope*, and, most of all, pursuant to common sense.

Similarly apparent was the unlawfulness of interfering with Linda and Charles Ande's right to procreation or contraception. C.E.A.'s positive CF test in 1993 had given them a one in four chance of giving birth to another child with CF. It is beyond reproach to say that they would have benefitted from, and surely deserved, the right to make their procreative choice with complete information. And as they continue to be loving parents, they will never have the ability to make that life altering, familial decision with the information that was intentionally withheld from them.

It was clear in 1993 that all of the above conduct of this nature was unlawful despite no decision directly on point. Judge Cardozo explained that "every human being of adult years and sound mind has a right to determine what shall be done with his own body" in relation to medical needs. *Washington v. Glucksberg*, 521 U.S. 702, 117 S.Ct. 2258, 2288 (1997) (Souter, J. concurring); quoting *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 129, 105 N.W. 92, 93 (1914).

In re Cincinnati Radiation Litigation, 874 F.Supp. 796, 812-13 (S.D. Ohio 1995), contains a thorough discussion of the line of cases dealing with the right to bodily integrity, demonstrating that the unlawfulness of the conduct at issue in this case should have been apparent to the researchers by the time C.E.A. was born on July 13, 1993:

> In 1990, the Supreme Court unequivocally held that the "forcible injection of medication into a non-consenting person's body represents a substantial interference with that person's liberty." *Washington v. Harper*, 494 U.S. 210, 229, 110 S.Ct. 1028, 1041, 108 L.Ed.2d 178 (1990). Still, other cases support the recognition of a general

liberty interest in refusing medical treatment. *Riggens v. Nevada*, 504 U.S. 127, 112 S.Ct. 1810, 118 L.Ed.2d 479 (1992) (forced administration of antipsychotic medication during trial violated Fourteenth Amendment); *Youngberg v. Romeo*, 457 U.S. 307, 315, 102 S.Ct. 2452, 2457-58, 73 L.Ed.2d 28 (1991) (government has duty to protect involuntarily committed mental patients from physical assault)

* * *

Parham v. J.R., 442 U.S. 584, 600, 99 S.Ct. 2493, 2503, 61 L.Ed.2d 101 (1979) ("[A] child, in common with adults, has a substantial liberty interest in not being confined unnecessarily for medical treatment"); *Whalen v. Roe*, 429 U.S. 589, 97 S.Ct. 869, 51 L.Ed.2d 64 (1977) (Constitution protects personal autonomy "in making certain types of important decisions"); *Schmerber v. California*, 384 U.S. 757, 772, 86 S.Ct. 1826, 1836, 16 L.Ed.2d 908 (1966) ("The integrity of the individual person is a cherished value of our society"); *Rochin v. California*, 342 U.S. 165, 171, 72 S.Ct. 205, 209, 96 L.Ed. 183 (1952) (the forcible extraction of stomach contents shocks the conscience and violates due process). See also *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 278, 110 S.Ct. 2841, 2851, 111 L.Ed.2d 224 (1989) (Fourteenth Amendment has been held to include medical decision-making, reflecting the "principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment.")

The one thing that the above cases make crystal clear is that the integrity of a person's body may not be violated. Violating the integrity of a person's body, taking away the

ability to direct one's medical care, depriving one of the ability to refuse medical treatment, destroying one's ability to make an informed decision about whether or not to procreate given a substantial risk of diseased offspring – all of these are rights which have been cherished. They have all been declared to be so fundamentally a part of our basic notions of liberty and autonomy that we have given them unwavering constitutional protection. It stretches credulity to argue that the unlawfulness of knowingly and intentionally malnourishing C.E.A. and preventing her from directing her medical care in the unquestionably most beneficial way was not apparent, simply because those violations were inflicted by withholding treatment and information, rather than by giving treatment or information.

C. Because the violation is so obvious and shocking, there need not be closely analogous cases with materially similar facts.

Even if there was not a single published decision relating to informed consent or the right to control medical care, it would not matter. The conduct at issue in this case is so egregious, and so stunning, that there need not be any factually similar case at all. The Seventh Circuit Court of Appeals has recognized that the most reprehensible cases will never reach litigation, much less publication. If closely analogous cases were required before a defendant could be charged having received fair warning, the most outrageous conduct we can imagine would be insulated from liability. "In fact, in the most extreme cases, an analogous case might never arise because the existence of the right was so clear, as a matter of the working of a constitutional or statutory provision or decisions in other

circuits or in the state courts, that no one thought it worthwhile to litigate the issue." *C.A. Brokaw v. Mercer County*, 235 F.3d 1000, 1022 (7th Cir. 2000); citing *Burgess v. Lowery*, 201 F.3d 942, 945 (7th Cir. 2000).

In *Rochin v. People of California*, 342 U.S. 165, 72 S.Ct. 205 (1952), this Court first set forth the principal that some conduct is simply too shocking "to permit of constitutional differentiation." *Id.* at 210. In *Rochin*, three deputy sheriffs forcibly entered Rochin's room, and unsuccessfully tried to extract drugs from his mouth. *Id.* at 206. Rochin was then handcuffed and taken to the hospital, where a doctor (at the direction of an officer) forced an tube into Rochin's stomach and administered a fluid that induced vomiting. *Id.* Two capsules of narcotics were recovered out of the vomit. *Id.* Rochin was convicted of possessing morphine. *Id.*

This Court found the conduct so shocked the conscience, that it could be nothing other than unconstitutional:

> [W]e are compelled to conclude that the proceedings by which this conviction was obtained do more than offend some fastidious squeamishness or private sentimentalism about combating crime too energetically. *This is conduct that shocks the conscience*. Illegally breaking into the privacy of the petitioner, the struggle to open his mouth and remove what was there, the forcible extraction of his stomach's contents – this course of proceeding by agents of government to obtain evidence is bound to offend even hardened sensibilities. They are methods too close to the rack and the screw to permit of constitutional differentiation.

Id. at 209 (emphasis added).

Although previous criminal convictions had been set aside because of coerced verbal confessions (merely words) rather than forcibly extracted physical evidence ("real evidence"), the Supreme Court was able to see the forest through the trees, and explained that coerced verbal confessions are "constitutionally obnoxious not only because of their unreliability. They are inadmissible under the Due Process Clause even though statements contained therein may be independently established as true. Coerced confessions offend the community's sense of fair play and decency." *Id.* at 210. "Shocks the conscience," "offends the community's sense of fair play and decency," "constitutionally obnoxious" – each and every one applies to the case at bar. It would be hard to imagine that if 100 people were told the story of what the Respondents had done to C.E.A. and her parents, that a single reasonable mind would disagree with that conclusion. This story does not evoke mere fastidious squeamishness. It is the kind of moral outrage and shocking disbelief that sends shivers down one's spine. Knowingly harming human babies, without full disclosure, in the name of completing some statistical data requirement for a state run medical experiment – with due awareness and respect for those who suffered the atrocities committed by German physicians during World War II – the conduct at issue in this case harkens back to the medical experiments conducted on prisoners, which later gave rise to the Nuremberg trials and the Nuremberg Code.

"The Nuremberg tribunal was asked to determine the culpability of twenty-three (23) German physicians under 'the principles of the law of nations as they result from the usages established among civilized peoples, from the laws of humanity, and from the dictates of public conscience.' The charges against the physicians included human

experimentation involving nonconsenting prisoners. The experiments included studies of the limits of human tolerance to high altitudes and freezing temperatures. Medically-related experiments included inoculation of prisoners with infectious disease pathogens and tests of new antibiotics. Various experiments involving the mutilation of bone, muscle, and nerve were also performed on nonconsenting prisoners." *In re Cincinnati Radiation Litigation*, 874 F.Supp. 796, 820 (S.D. Ohio 1995).

"Throughout the trial, the question of what were or should be the universal standards for justifying human experimentation recurred." *Id.* As a result of the Nuremberg trial, the Nuremberg Code was developed. The first provision of the Code states:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice . . . and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of any affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health and person which may possibly come from his participation in the experiment.

"The Nuremberg Code is part of the law of humanity. It may be applied in both civil and criminal cases by the federal courts of the United States." *Id.* at 821.

Decades later, despicable medical experimenting by the United States Army caused this law of humanity to be invoked by Justices O'Connor and Brennan in *United States v. Stanley*, 483 U.S. 669, 107 S.Ct. 3054 (1987). Stanley, a master sergeant in the Army volunteered for what he thought was a test of protective clothing and equipment against chemical warfare. *Id.* at 3057. Once at the Army's Chemical Warfare Laboratory in Maryland, he was secretly administered doses of LSD, pursuant to an Army plan to study the effects of the drug on human subjects. *Id.* As a result, Stanley suffered hallucinations, memory loss, insomnia, and other effects which led to the break up of his marriage. *Id.*

The majority ultimately found the individuals in charge of the study were not liable for money damages because the injury was "incident to service". *Id.* at 3063-65. In his powerful dissent, Justice Brennan cautioned that when immunity prevents liability in a case as egregious as *Stanley*, "Government officials remain free to violate the constitutional rights of soldiers without fear of money damages. What this case and others like it demonstrate, however, is that Government officials (military or civilian) must not be left with such freedom." *Id.* at 3068 (Brennan, J. dissenting). So it is in the case at bar.

Justice O'Connor penned similarly strong language condemning experiments which dupe the human subject:

> "No judicially crafted rule should insulate from liability the involuntary and unknowing human experimentation alleged to have occurred in this case. Indeed . . . the United States military played an instrumental role in the criminal prosecution of Nazi officials who experimented with human subjects during the Second World War, and the standards that the Nuremberg

> Military Tribunals developed to judge the behavior of the defendants stated that the 'voluntary consent of the human subject is absolutely essential . . . to satisfy moral, ethical, and legal concepts. . . . If this principle is violated the very least society can do is to see that the victims are compensated, as best they can be, by the perpetrators. I am prepared to say that our Constitution's promise of due process of law guarantees this much."

(*Id.* at 3066) (O'Connor, J. dissenting) (internal citations omitted).

The lower court decisions in this case have turned qualified immunity into absolute immunity, and that must not stand. To condone the respondents' conduct in this case, which has found shelter under the umbrella of qualified immunity, "would be to afford brutality the cloak of law. Nothing would be more calculated to discredit law and thereby to brutalize the temper of society." *Rochin*, supra, at 173-74.

D. The liberty interests raised by petitioners are identifiable and protected under the due process clause of the Fourteenth amendment.

In the proceedings below, Petitioner identified three (3) liberty interests violated by the conduct of the respondent researchers. These liberty interests were: 1) the right to bodily integrity; 2) the right to make decisions relevant to procreation and contraception; and 3) protection against government intrusion into the right of familial association. If the facts of this case as alleged by Petitioners are taken as true, as they must be for purposes of summary judgment, then it is unequivocal that there is a liberty interest violation.

Both the trial court and the Wisconsin Court of Appeals assumed, without deciding, that Petitioners could establish the violation of a liberty interest. The appellate court then dismissed the claims under the affirmative defense of qualified immunity.

This Court has recognized "a right of personal privacy or a guarantee of certain areas or zones of privacy does exist under the Constitution." *Roe v. Wade*, 410 U.S. 113, 153, 93 S.Ct. 705, 727 (1973) *citing Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 251, 11 S.Ct. 1000, 1001 (1891). The roots of this right to privacy have, in part, been identified within the concept of liberty guaranteed within the Due Process Clause of the Fourteenth Amendment. *Id.; citing Meyer v. Nebraska*, 262 U.S. 390, 399, 43 S.Ct. 625, 626 (1923).

The rights protected within the "zone of privacy" guarantees of the Fourteenth Amendment include procreation, *Skinner v. Oklahoma*, 316 U.S. 535, 541-542, 62 S.Ct. 1110, 1113-1114 (1942); contraception, *Eisenstadt v. Baird*, 405 U.S. 438, 453-454, 92 S.Ct. 1029, 1038-1039 (1972); family relationships, *Prince v. Massachusetts*, 321 U.S. 158, 166, 64 S.Ct. 438, 442 (1944); to direct the rearing and education of one's child, *Pierce v. Society of Sisters*, 268 U.S. 510, 535, 45 S.Ct. 571, 573 (1925); *Meyer v. Nebraska*, 262 U.S. 390, 400, 43 S.Ct. 625, 627 (1923); the right to bodily integrity, *Rochin v. California*, 342 U.S. 165, 72 S.Ct. 205, (1952); the right to personal control of medical treatment, *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 278, 110 S.Ct. 2841, 2851 (1990); and right of parents to obtain needed medical treatment for their child, *Parham v. J.R.*, 442 U.S. 584, 604, 99 S.Ct. 2493, 2505 (1979). These cases reflect a tradition of protecting those rights associated with the

basic and intimate exercise of personal autonomy. *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 847, 112 S.Ct. 2791, 2804-2805 (1992).

CONCLUSION

For the reasons set forth above, the Petitioners respectfully urge this Court to grant certiorari.

Dated this 23rd day of October, 2002.

Respectfully submitted,

Linda A. Ande, Charles Ande and C.E.A., Their Minor Child

Petitioners

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COURT OF APPEALS
DECISION
DATED AND FILED

May 16, 2002

Cornelia G. Clark
Clerk of Court of Appeals

NOTICE

This opinion is subject to further editing. If published, the official version will appear in the bound volume of the Official Reports.

A party may file with the Supreme Court a petition to review an adverse decision by the Court of Appeals. *See* WIS. STAT. § 808.10 and RULE 809.62.

Cir. Ct. No. 98-CV-1634

Appeal No. 01-1009

STATE OF WISCONSIN

IN COURT OF APPEALS DISTRICT IV

LINDA A. ANDE, CHARLES ANDE, C.E.A., A MINOR, AND C.L.A., A MINOR,

PLAINTIFFS-APPELLANTS,

V.

MICHAEL ROCK, NORMAN C. FOST, PHILIP M. FARRELL, ELAINE H. MISCHLER, RICHARD A. ARONSON, AND ANITA LAXOVA,

DEFENDANTS-RESPONDENTS,

UW HOSPITAL AND CLINICS, UW MEDICAL SCHOOL, WISCONSIN DEPARTMENT OF HEALTH & SOCIAL SERVICES, MEDICAL COLLEGE OF WISCONSIN-MILWAUKEE, WISCONSIN STATE LABORATORY OF HYGIENE, STATE OF WISCONSIN, RONALD LAESSIG, KAREN KEIL, M. COTLER, C. KELLY, S. ALLARD, ELLEN CONNOR,

DAVID B. ALLEN, E. CONNOR, TOM MURWIN, L. REIMANN, GORDON TUFFLI, GURBAX SEKHOM, MICHAEL R. KOSOROK, REBECCA E. KOSCIK, MARK SPLAINGARD, C. GREEN, M. PALTA, A. TLUCZEK, M. BLOCK, L. A. DAVIS, B. S. WILFOND, W. GERSHAN, L. RUSAKOW, G. HOFFMAN, D. J. HASSEMER, JOHN DOE, JANE DOE, XYZ FUNDING AGENCY, CONNECTICUT GENERAL LIFE INSURANCE COMPANY, ABC INSURANCE COMPANY, AND UNITY HEALTH PLANS;

DEFENDANTS.

APPEAL from a judgment and an order of the circuit court for Dane County: ROBERT DeCHAMBEAU, Judge. *Affirmed.*

Before Dykman, Roggensack and Deininger, J.J.

¶1 ROGGENSACK, J. Linda A. Ande, Charles Ande and their minor children, C.E.A. and C.L.A. who suffer from cystic fibrosis, brought suit against individual defendants, all of whom are state employees, and certain institutions alleging numerous state and federal claims related to the children's cystic fibrosis. The circuit court dismissed all of the state claims, except those for medical malpractice, after concluding that notice pursuant to Wis. Stat. § 893.82(3) (1995-96)[1] for those state claims had not been timely given. In regard to the medical malpractice

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[1] All references to the Wisconsin Statutes are to the 1995-96 version unless otherwise noted.

claims, the circuit court dismissed them because there was no showing of a physician-patient relationship between the remaining physician-defendants and any plaintiff.[2] The circuit court also dismissed the federal claims, doing so on the basis of qualified immunity because the plaintiffs had not shown that any plaintiff had a clearly established right that any defendant's conduct violated. On appeal, the plaintiffs do not contest the circuit court's decision on the lack of timely notice under § 893.82(3). Plaintiffs bring before us for review only their claims for medical malpractice and their federal claims. Because we conclude that plaintiffs have made no showing of a physician-patient relationship with any remaining defendant, which relationship is necessary to support a medical malpractice claim, and that plaintiffs have made no showing of a clearly established state property right or a clearly established state or federal liberty interest that any named defendant's conduct violated, we affirm the judgment and order of the circuit court.

BACKGROUND

¶2 C.E.A. was born to Linda and Charles Ande on July 13, 1993. There was then ongoing a cystic fibrosis research project which had begun in 1985. Philip Farrell and Norman Fost were the co-investigators. To test for the

[2] Numerous defendants were voluntarily dismissed by stipulation both before and after the circuit court's decision on defendants' summary judgment motion. Additionally, appellants have chosen not to appeal the circuit court's decision as to many other defendants. Consequently, this appeal involves the appeal of claims against only the following defendants: Michael Rock, Norman C. Fost, Philip M. Farrell, Elaine H. Mischler, Richard A. Aronson and Anita Laxova.

presence of factors indicative of cystic fibrosis, the study used excess blood that had been drawn from all newborns to conduct statutorily required tests for the presence of other congenital and metabolic disorders. The research protocol required that the parents of half of the newborns in the study were told if their child tested positive for cystic fibrosis. A nutritional plan was made available to them immediately, as it was the researchers' theory that treating the nutritional needs of children with cystic fibrosis before they became symptomatic would result in a less vigorous development of the disease with fewer impairments to overall health. The other half of the children who were tested were placed in the "blinded control" group. Their parents and their treating physicians were not told if they had tested positive for factors indicative of cystic fibrosis. C.E.A. was placed in the blinded group, and therefore, her parents and her primary physician, Dr. Amy Plumb, were not told that she had tested positive.

¶3 Prior to testing the blood of newborns for cystic fibrosis, a pamphlet was prepared that told about the different tests that were required to be completed on newborns' blood. It also told of the cystic fibrosis test that would be run as part of a research project. It described the dangers of cystic fibrosis and stated that cystic fibrosis was an inherited disorder. The pamphlet also arguably implied that positive test results would be reported to the infant's physician, and a phone number was listed for parents who wanted additional information about the

test.[3] There is no assertion that the Andes were asked for or gave specific, written consent to have the cystic fibrosis test run on C.E.A. or to have the results of that test go unreported to them.

¶4 Subsequent to birth, C.E.A. had difficulties thriving. On June 23, 1995, when C.E.A. was almost two years old, she was diagnosed with cystic fibrosis. At the time that the Andes learned that C.E.A. had cystic fibrosis, Linda Ande was pregnant with a second child. The Andes' second child, C.L.A., is also afflicted with cystic fibrosis.

¶5 In this lawsuit, the Andes' allegations may be summarized into the assertion that the defendants committed three wrongful acts that give rise to the Andes' various claims: (1) The cystic fibrosis test was run without their informed consent; (2) treatment was withheld from C.E.A. when the investigators had knowledge that nutritional treatment would reduce the severity of her cystic fibrosis; and (3) C.E.A.'s test results were withheld from them. They allege to have been harmed by these acts in two ways: (1) If they had been given the test results, they

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[3] The brochure was revised numerous times, with differing disclosures listed in each version. The edition that plaintiffs' attorneys aver was presented to the Andes states:

> One-half of the blood samples are tested for CF before the babies are one month old. The remaining blood samples are partially tested at this time. Testing on these blood samples is completed when the children are 4 years old. Positive test results are reported to your child's doctor.
>
> If the CF research test is done, you may contact your doctor, certified nurse-midwife, or the CF specialist at (608) 263-8555 for the result.

would have accepted treatment for C.E.A. to lessen the severity of the progression of her illness; and (2) if they had been given the test results, they would not have conceived C.L.A. They do not identify any harm they suffered from the alleged lack of informed consent to run the test in the first instance.

¶6 In response, the defendants assert that they did not test C.E.A.'s blood without the Andes' knowledge and consent. They also contend that although all the children in the blinded control group were tested as newborns, no one reviewed the test results for the control group, some of which were negative and some of which were positive for factors indicative of cystic fibrosis. Therefore, the defendants contend they did not withhold information from the Andes.[4] The defendants also raised many affirmative defenses, including failure to state a claim and qualified immunity.

¶7 After some discovery had been completed, the defendants moved for summary judgment, which the circuit court granted. It concluded that the plaintiffs gave WIS. STAT. § 893.82(3) notice too late to preserve their state claims, except for medical malpractice,[5] and that the

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[4] There is a clear factual dispute on what defendants knew and when they knew it, but it relates only to the plaintiffs' state claims such as the alleged breach of the researchers' duty to warn. Because the plaintiffs have not appealed the circuit court's decision that notice of claim was given more than 120 days after these state claims arose, this factual dispute is not material to the disposition of the appeal.

[5] A notice of claim for medical malpractice against these defendants could have been filed up to 180 days after it arose. WIS. STAT. § 893.82(5m). A notice of claim for other types of negligence must have been filed within 120 days. Section 893.82(3). This longer period for

(Continued on following page)

Andes' medical malpractice claims could not proceed because none of the remaining defendants had a physician-patient relationship with any plaintiff. The circuit court also dismissed plaintiffs' federal claims on the basis of qualified immunity. The plaintiffs moved for reconsideration and the circuit court denied their motion. The plaintiffs appeal only the dismissal of their medical malpractice claims and their federal claims.

Standard of Review.

¶8 It is well established that we apply the same summary judgment methodology as the circuit court. ***Smith v. Dodgeville Mut. Ins. Co.***, 212 Wis. 2d 226, 232, 568 N.W.2d 31, 34 (Ct. App. 1997). We first examine the complaint to determine whether it states a claim,[6] and then we review the answer to determine whether it joins a material issue of fact or law. ***Id.*** If we conclude that the complaint and answer are sufficient to join issue, we examine the moving party's affidavits to determine whether they establish a *prima facie* case for summary judgment. ***Id.*** at 232-33, 568 N.W.2d at 34. If they do, we look to the opposing party's affidavits to determine whether there are any material facts in dispute which entitle the opposing party to a trial. ***Id.***

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filing a notice of claim under subsection (5m) was the basis for the circuit court's conclusion that the notice of claim for medical malpractice was timely.

[6] For example, whether the allegations in the complaint are sufficient to give rise to a physician-patient relationship supportive of a malpractice claim is a question of law we review *de novo*.

¶9 Whether the Andes have shown the existence and deprivation of a clearly established right by citing "closely analogous" cases that would give a reasonable public official notice that his actions clearly violated a right protected by the United States Constitution or by a federal statute is also a question of law. *See* ***Hunter v. Bryant***, 502 U.S. 224, 227-28 (1991) (per curiam); ***Burkes v. Klauser***, 185 Wis. 2d 308, 327-32, 338-39, 517 N.W.2d 503, 511-13, 516 (1994).

Medical Malpractice.

¶10 Medical malpractice arises when a physician fails to exercise that degree of care and skill usually employed by the average practitioner under similar circumstances. *See* ***Johnson v. Misericordia Cmty. Hosp.***, 97 Wis. 2d 521, 543-44, 294 N.W.2d 501, 513 (Ct. App. 1980), *aff'd*, 99 Wis. 2d 708, 301 N.W.2d 156 (1981). Whether a suit for malpractice will lie against a specific physician depends upon whether there is a physician-patient relationship between that physician and the complainant. *See, e.g.*, ***Froh v. Milwaukee Med. Clinic, S.C.***, 85 Wis. 2d 308, 311, 270 N.W.2d 83, 84 (Ct. App. 1978). A physician-patient relationship is a trust relationship, created when professional services are provided by a physician and accepted by a patient. *See* ***Brown v. Dibbell***, 227 Wis. 2d 28, 46-47, 595 N.W.2d 358, 368 (1999). Only a physician "who treats a patient" is charged with a statutory duty to inform the patient about treatment modalities and the benefits and risks of those treatments. WIS. STAT. § 448.30.

¶11 Our summary judgment review starts with an examination of the Second Amended Complaint relative to

the physicians against whom the Andes maintain claims in this appeal. While the first claim for relief is styled "MEDICAL MALPRACTICE," the substantive allegations of wrongdoing focus only generally on "the defendants." Paragraph 41 alleges "negligence" due to the "failure to obtain informed consent from the Andes before proceeding with the study and [the] failure to timely diagnos[e][7] and inform the Andes that C.E.A. had cystic fibrosis." (Footnote added.) Paragraph 40 also incorporates all allegations made in paragraphs 1-39, none of which describes the provision or receipt of medical services or the request for services that were not provided. The general tenor of those paragraphs is that defendants had information that they had a duty to disclose to plaintiffs. In sum, the medical malpractice claim is based on the alleged failure to obtain informed consent to run the test in the first instance and the failure to provide information after it was run. However, even if we were to assume *arguendo* that the researchers had a duty to obtain informed consent from the Andes, that the pamphlet that was provided was insufficient to do so, and that they had a duty to share what information was available to them with the Andes, there is no allegation in the complaint of any relationships between the Andes and any of the researchers from which one could conclude that such duties arose from a physician-patient relationship, rather than from ordinary negligence principles.

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[7] This part of the claim was initially focused on Dr. Amy Plumb and others who treated C.E.A. However, Dr. Plumb was dismissed by stipulation prior to the circuit court's decision on summary judgment, and the Andes have accepted the dismissal of all of the other physicians who were involved in C.E.A.'s treatment.

¶12 Additionally, uncontradicted materials submitted in the circuit court by the respondents during the summary judgment proceedings show that Aronson is the Chief Medical Officer for Family and Community Health for the Wisconsin Division of Public Health within the Wisconsin Department of Health and Family Services. He was not engaged in the practice of medicine, did not render primary care to any patients and had no authority or responsibility to direct or control the cystic fibrosis research study which is central to this lawsuit. All of the remaining defendants appear to have been connected with the cystic fibrosis research project in some manner, but they had no relationship with the Andes. For example, Farrell was the Dean of the University of Wisconsin Medical School and, together with Fost, was a co-investigator for the cystic fibrosis study. Plaintiffs have provided no affidavit or other evidentiary proof to show any physician-patient relationship between the Andes and any defendant who is subject to this appeal. Accordingly, we conclude that the circuit court correctly dismissed plaintiffs' claims for medical malpractice.

Federal Claims.

¶13 The Andes' federal claims invoke 42 U.S.C. § 1983 (1994).[8] They claim a due process violation because

[8] 42 U.S.C. § 1983 (1994) provides in relevant part:

Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall

(Continued on following page)

the defendants deprived them of their liberty and property interests by arbitrarily placing C.E.A. in the blinded control group of the cystic fibrosis study and withholding her test results from them for almost two years, during which time beneficial treatment was withheld from C.E.A. and the Andes conceived another child who also has cystic fibrosis. The respondents contend that the Andes' claims may not proceed because they are protected by qualified immunity.

1. 42 U.S.C. § 1983 overview.

¶14 Section 1983, in and of itself, does not create substantive rights; rather, it provides a remedy for the deprivation of rights that are established elsewhere. ***Chapman v. Houston Welfare Rights Org.***, 441 U.S. 600, 617-18 (1979). In a § 1983 claim that alleges a violation of either procedural or substantive due process, a plaintiff must show a deprivation of an interest in life, liberty or property that is protected by the Constitution. ***Penterman v. Wisconsin Elec. Power Co.***, 211 Wis. 2d 458, 473, 565 N.W.2d 521, 533 (1997). Although the Andes allege the deprivation of substantive rights, based on what they characterize as the withholding of medical information about C.E.A., they are not clear about whether their due process claims implicate a property interest or a liberty interest.[9] We will examine each interest in turn.

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be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress.

[9] Paragraph 34 of the Second Amended Complaint alleges that "[t]he Andes had a property and/or liberty interest in knowing that C.E.A. was being placed in the study at the time she was placed in it; in

(Continued on following page)

2. *Qualified immunity overview.*

¶15 Qualified immunity may preclude claims against a government official for the performance of discretionary functions if the official's conduct does not violate a clearly established federal statutory or constitutional right. ***Harlow v. Fitzgerald***, 457 U.S. 800, 818 (1982); ***Penterman***, 211 Wis. 2d at 469, 480, 565 N.W.2d at 528. Additionally, even though qualified immunity is an affirmative defense, a plaintiff must be able to demonstrate by closely analogous case law that the defendant's alleged conduct constituted a violation of a clearly established federal statutory or constitutional right at the time the acts occurred. ***Penterman***, 211 Wis. 2d at 469, 565 N.W.2d at 528. Accordingly, if a reasonable person in the position of the defendants could have believed that the manner in which he conducted the cystic fibrosis study did not violate the plaintiffs' rights at the time the test on C.E.A. was conducted and that not informing the Andes of the test results until 1995 did not violate the Andes' liberty or property interests, qualified immunity protects the defendants from liability arising from the Andes' claims brought under federal law. *See* ***Hunter***, 502 U.S. at 227-28. "The qualified immunity standard 'gives ample room for

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knowing the nature of the study and the ramifications of participation before C.E.A. was placed in the study; and in knowing that she had cystic fibrosis at or near the time that diagnosis was made." In paragraph 75, the Andes allege that they were denied "their property right to information about C.E.A.'s medical condition (cystic fibrosis)." And paragraph 76 alleges that the defendants denied the Andes' children their "respective liberty interests in maintaining their health and their bodily integrity."

mistaken judgments' by protecting 'all but the plainly incompetent or those who knowingly violate the law.'" ***Id.*** at 229 (quoting ***Malley v. Briggs***, 475 U.S. 335, 343, 341 (1986)).

3. Violation of a clearly established right.

a. Property interest.

¶16 The first step in our analysis is to determine whether the Andes had a substantive property right to receive the results of C.E.A.'s cystic fibrosis test at or near the time it was performed. *See* ***Arneson v. Jezwinski***, 225 Wis. 2d 371, 386, 592 N.W.2d 606, 613 (1999). Substantive property interests are created exclusively under state law. ***Id.*** Therefore, in order to determine whether the Andes had a substantive property interest in the test results, we look to Wisconsin law. However, federal constitutional law determines whether a state-created property interest rises to a "legitimate claim of entitlement" under the Due Process Clause of the United States Constitution. ***Id.*** (quoting ***Memphis Light, Gas & Water Div. v. Craft***, 436 U.S. 1, 9 (1978)). Federal law also determines how much procedural due process must be provided before one may be deprived of a protected property right. ***Arneson***, 225 Wis. 2d at 386, 592 N.W.2d at 614.

¶17 Because a qualified immunity examines the status of the right asserted at the time it was allegedly denied, we must determine whether prior to June 26, 1995,[10] the Andes had a property right under Wisconsin

[10] The Andes learned the results of C.E.A.'s initial cystic fibrosis test on June 26, 1995; however, she was diagnosed with cystic fibrosis on June 23, 1995, through tests run on that date.

law, that was then clearly established, to have received the test results. The Andes have cited no Wisconsin case to us which holds that they had a property interest in the test results of the cystic fibrosis study, nor have they cited any cases which are closely analogous. Additionally, our research has uncovered no such Wisconsin case that predates the disclosure of the information to the Andes in 1995. Accordingly, we conclude there was no such property right under Wisconsin law that was clearly established prior to June 26, 1995 when the test results were disclosed. Accordingly, the Andes have failed to establish the first step necessary to a due process claim based on the deprivation of a clearly established property right and therefore, their claim in this regard was properly dismissed.

b. Liberty interest.

¶18 The Andes also allege a constitutional violation of a liberty interest based on the failure to obtain informed consent for the testing that was done, as well as on the alleged failure to disclose information. Liberty interests may arise under either state[11] or federal[12] law. For example, the Fourteenth Amendment of the United States

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[11] *See* ***State ex rel. Gendrich v. Litscher***, 2001 WI App 163, ¶6, 246 Wis. 2d 826, 632 N.W.2d 878 (state liberty interests are decided on a case-by-case basis).

[12] *See* ***Cruzan v. Director, Mo. Dept. of Health***, 497 U.S. 261, 278 (1990) (a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment); ***Harris v. McRae***, 448 U.S. 297, 311-12 (1980) (liberty interests protected by the Due Process Clause include a freedom of personal choice in certain matters of marriage and family life).

Constitution protects an "individual interest in avoiding disclosure of personal matters." ***Hillman v. Columbia County,*** 164 Wis. 2d 376, 400, 474 N.W.2d 913, 922 (Ct. App. 1991) (quoting ***Whalen v. Roe,*** 429 U.S. 589, 599-600 (1977)). This personal liberty interest arises from a "guarantee" under federal law of certain zones of privacy. ***Roe,*** 429 U.S. at 598-600 & n.23. The Supreme Court has also recognized that there is a constitutionally protected liberty interest in bodily integrity and in the right to determine what medical treatment shall be accepted or refused, *see* ***Washington v. Glucksberg,*** 521 U.S. 702, 777 (1997) (Souter, J., concurring), and that parents have a constitutionally protected right to obtain needed medical treatment for their child so long as the child's rights are protected by the process employed. *See* ***Parham v. J.R.,*** 442 U.S. 584, 602 (1979). While neither the Wisconsin Supreme Court nor the United States Supreme Court has yet addressed whether there is a constitutionally protected liberty interest in receiving information from a research project relative to one's genetic predisposition to give birth to a child with a genetically transmitted disorder or in receiving information from a research project that would assist a parent in making informed health care choices for his or her child, we cannot say with certainty that the withholding of the results of C.E.A.'s test did not implicate a liberty interest in either the parents or C.E.A. Therefore, for purposes of our discussion we shall assume, without deciding, that a liberty interest could be established if this case were to go to trial.

¶19 Once a liberty interest has been established, it may not be denied without a federally acceptable amount of procedural due process. ***Arneson,*** 225 Wis. 2d at 399, 592 N.W.2d at 619. In regard to the alleged failure to

obtain informed consent before the cystic fibrosis test was run in the first instance, the Andes base none of their claimed injuries on an unauthorized disclosure of private information, as they might if the researchers had disclosed C.E.A.'s condition to third parties. And they identify no harm that they suffered by not giving consent to the test in the first instance. For example, they do not allege that they would not have permitted the test if they had known it was being conducted. Instead, all of their alleged injuries flow from not having the *results* of the test at or near the time it was conducted. Therefore, we will not address their claims in regard to an alleged lack of informed consent further.[13]

¶20 We now turn to the alleged failure to timely disclose the results of C.E.A.'s cystic fibrosis test. The closest the Andes come in making an argument that the alleged failure to disclose was a clear violation of their rights is to contend that one of the defendants, Richard Aronson, as the Medical Director for the Wisconsin Newborn Screening Program conducted under the direction of the Wisconsin Department of Health and Family Services,

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[13] We note that developing appropriate recommendations for obtaining adequate informed consent when gathering tissue samples that may later be used for genetic studies and determining when additional consent should be required for tissue samples already collected have been the subject of some debate. *See* Ellen Wright Clayton et al., *Informed Consent for Genetic Research on Stored Tissue Samples,* 274 JAMA 1786 (1995). Additionally, at the time relevant to the Andes' claims, federal law permitted certain research on some types of tissue samples without informed consent, if the tissue samples had already been collected and the subjects from whom the samples had been obtained could not be identified. *See* 45 C.F.R. § 46.101(b)(4) (1994).

had a statutory duty under WIS. STAT. § 253.13(5) to disclose the results of the testing for congenital disorders. Section 253.13(5) stated in relevant part:

> The department shall disseminate information to families whose children suffer from congenital disorders and to women of child-bearing age with a history of congenital disorders concerning the need for and availability of follow-up counseling and special dietary treatment and the necessity for testing infants. The department shall also refer families of children who suffer from congenital disorders to available health and family services programs and shall coordinate the provision of these programs. The department shall periodically consult appropriate experts in reviewing and evaluating the state's infant screening programs.

In 1993, the year C.E.A. was born, WIS. ADMIN. CODE § HSS 115.04 (1993) set out the tests to be done and for which information was required to be provided under § 253.13. Cystic fibrosis was not then a required test under § HSS 115.04.[14] By emergency rule, effective January 31, 1995,[15] cystic fibrosis was added to the list of tests that were required to be performed on newborns, *see* § HSS

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[14] In 1993, Wisconsin law required screening of all newborns in the state for biotinidase deficiency, congenital adrenal hyperplasia, congenital hypothyroidism, galactosemia, phenylketonuria and sickle cell disease. *See* WIS. STAT. § 253.13 (1993-94); WIS. ADMIN. CODE § HSS 115.04 (1993).

[15] According to Aronson's deposition testimony and affidavit, routine screening for cystic fibrosis actually commenced in April 1994, which was several months prior to the effective date of the emergency rule.

115.04 (1995), and the Andes were not given C.E.A.'s test results until mid-1995. However, even if we were to conclude that § 253.13 could be construed to implicate a liberty interest to receive results of a cystic fibrosis test conducted a year before the testing and reporting of the results became mandatory, the failure to disclose cannot be said to rise to the level of a violation of a "clearly established" right because there is no closely analogous case law which interprets § 253.13 to require the disclosure of tests run before the statute and applicable administrative rules required them.

¶21 The Andes also allege a "general" violation of substantive due process, claiming that the actions of the defendants were arbitrary and capricious in the way in which they selected C.E.A. for the control group and failed to disseminate the information they had about her. Substantive due process protects individuals from arbitrary, wrongful, governmental actions regardless of the process afforded prior to the deprivation. ***Penterman***, 211 Wis. 2d at 480, 565 N.W.2d at 533. The Supreme Court has repeatedly explained that the touchstone of substantive due process is the protection of the individual against arbitrary action of government. ***County of Sacramento v. Lewis***, 523 U.S. 833, 845-46 (1998). Substantive due process protects against governmental actors who engage in conduct that "shocks the conscience" or conduct which interferes with rights "implicit in the concept of ordered liberty." ***Id.*** at 846-47 (quoting ***Rochin v. California***, 342 U.S. 165, 172 (1952)). However, even so generalized a claim of protection still requires the identification of a clearly protected interest that the actor's conduct violates. Due process claims are not a substitute for general tort claims. ***Lewis***, 523 U.S. at 846 n.8. The Andes have failed to

identify any Wisconsin or federal case law clearly establishing such an interest. Therefore, we conclude that qualified immunity bars all their federal claims.[16]

CONCLUSION

¶22 Because we conclude that plaintiffs have made no showing of a physician-patient relationship with any remaining defendant, which relationship is necessary to support a medical malpractice claim, and that plaintiffs have made no showing of a clearly established state property right or a clearly established state or federal liberty interest that any named defendant's conduct violated, we affirm the judgment and order of the circuit court.

By the Court. – Judgment and order affirmed.

Recommended for publication in the official reports.

[16] The Andes do not address the circuit court's denial of their motion for reconsideration as a separate argument. Therefore, we conclude that there was no erroneous exercise of discretion in denying the motion, for the reasons stated above.

CIRCUIT COURT
Branch 1

STATE OF WISCONSIN **DANE COUNTY**

LINDA A. ANDE, CHARLES ANDE, C.E.A. (a minor), and C.L.A. (a minor),

Plaintiffs,

vs.

MICHAEL ROCK, et al., Defendants.

MEMORANDUM DECISION AND ORDER
Case No. 98 CV 1634

(Filed Apr. 9, 2001)

MOTION TO RECONSIDER

This matter is before the court on Plaintiffs' motion for reconsideration of the court's January 11, 2001 decision granting summary judgment to the State Defendants. The court has carefully reviewed and reconsidered all the pleadings, briefs, affidavits, and exhibits that were part of the case prior to January 11, 2001. However, for the reasons set forth herein, the court sustains its original decision.

Plaintiffs have submitted affidavits with evidentiary exhibits attached to their briefs on the motion to reconsider. However, they did not provide the court with any explanation, let alone satisfactory, as to why Plaintiffs were unable, through due diligence, to present that evidence to the court during the pendency of the motions for summary judgment. *See Rothwell Cotton Company v. Rosenthal & Company,* 827 F.2d 246, 251-52 (7th Cir.

1987). The court therefore declines to consider such evidence.

DISCUSSION[1]

The court has, to the best of its ability, attempted to make sense out of Plaintiffs' briefs on the motion to reconsider. Plaintiffs' [sic] appear to argue as follows: since Defendants knew that what they were doing was wrong, they must have known that they were violating Plaintiffs' clearly established constitutional or statutory rights, and thus, the defense of qualified immunity cannot apply to the State Defendants' conduct. Plaintiffs also assert that a jury should be charged with determining at what point Defendants knew what they were doing violated Plaintiffs' rights.

However, the court finds that there is no jury question here. First, Defendants conceded the facts as alleged by Plaintiffs for purposes of their summary judgment motion. Additionally, the court finds that while Defendants were aware there were *ethical* questions involved in the design and implementation of the CFNSP[2], they did not know or suspect that it would violate a constitutional or statutory right. To the contrary, Defendants were persuaded of the ultimate potential for good to come out of the project.

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[1] The court recounted the factual background of this case in its previous decision, and sees no reason to repeat them here.

[2] "CFNSP," as indicated in the court's original decision, stands for Cystic Fibrosis Neonatal Screening Project.

Thus, they determined that the ethical questions were overcome by the benefits to be gained.

Defendants certainly did not believe that their plan to randomly place half of all newborns in a control group, whose members would receive no experimental treatment, would violate anyone's fundamental rights. What was obvious to the researchers was that they would have to obtain the informed consent of the parents of any child in the experimental group to whom they wanted to provide the experimental treatment. Therein lies the "meaningless distinction," as it was characterized by Plaintiffs at page 20 of their initial brief in support of the motion to reconsider, which the court makes between subjecting human research subjects to some type of *affirmative* treatment or procedure, and not doing anything other than what has always been done, which in this case amounted to leaving them alone.

Plaintiffs complain repeatedly that the researchers knew at some point that they were denying babies something of known value. In their brief, Plaintiffs contend that the researchers had that knowledge at the inception of the project. What Plaintiffs fail to understand is that of course the researchers believed in the benefits of the experimental treatment. If they hadn't, they would not have proposed the research. The point is, until the study was completed, the experimental treatment was just that, i.e., experimental. It could not be considered something of known value until the results of the completed study could prove it so.

The purpose of the research was first, to effect the inclusion of the IRT in the already existing newborn screening program. Without the routine screening for CF,

there would be no other pre-symptom indication that a child needed what is essentially a preventive treatment. In order to achieve their goal of making newborn CF screening routine, the researchers had to prove by scientifically accepted methods that there was a good reason for getting the information provided by the screening at the time of the screening. They needed to show that positive screening results would lead to beneficial treatment otherwise unavailable for failure to act within the window of opportunity, i.e., the child's pre-symptomatic state.

The court thus finds that the question of at what point the researchers knew their experimental treatment was "something of known value" is not the appropriate inquiry here. Rather, the proper question for purposes of Defendants' qualified immunity defense is whether, under the law existing at the time of Plaintiffs' alleged injuries, there was a cognizable constitutional or statutory right denied to Plaintiffs by Defendants, and if so, whether that right was so well established as to provide Defendants with notice that their conduct violated it. *Harlow v. Fitzgerald,* 457 U.S. 800, 818-19, 102 S.Ct. 2727, 73 L.Ed.2d 396 (1982).

It is Plaintiffs' burden to show that there was such a right. *Landstrom v. Illinois Dept. of Children and Family Services,* 892 F.2d 670, 675-76 (7th Cir. 1990). To do that, Plaintiffs must show a "sufficient consensus" of all relevant case law that Defendants' conduct was unlawful. *Id.*, at 676. Plaintiffs rail against that requirement, urging that Defendants' conduct falls under the exception to it outlined in *Brokaw v. Mercer County*, 235 F.3d 1000, 1022 (7th Cir. 2000). That exception allows that some conduct would be so obviously violative of fundamental rights that any reasonable state actor would realize that, and it would

thus not have spawned any litigation. *Brokaw,* 235 F.3d at 1022.

However, that is clearly not the case here. As noted by Defendants in their brief in opposition to the motion to reconsider, Plaintiffs' various arguments on their obligation to show "sufficient consensus" are inconsistent. On the one hand Plaintiffs have argued that cases they cited in their briefs opposing summary judgment, which they took great pains to analogize to the instant case, "stand for the common sense maxim that the State violates a persons [sic] constitutional rights if they [sic] subject humans to potential harm without consent" (Plaintiffs' brief at 7). On the other hand, Plaintiffs now argue that there are no closely analogous cases to the one at bar because of the obviously unlawful nature of Defendants' conduct. (Id.)

Plaintiffs have simply not demonstrated that there was a clearly established right against the type of non-affirmative, non-invasive conduct engaged in by Defendants. Nor have Plaintiffs shown that Defendants' failure to obtain Linda and Charles Ande's informed consent to not treat their daughter or to inform them of their daughter's positive IRT[3] violated a clearly established statutory right. At the very least, given the fact of the NIH[4] funding and the IRB's[5] ongoing approval of the project, it was objectively reasonable for Defendants to believe their

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[3] "IRT" stands for immunoreactive trypsinogen, which is the screening test for CF that Defendants proposed to make a routine part of the existing newborn screening program.

[4] National Institutes of Health.

[5] Institutional Review Board, required to oversee projects funded by the NIH.

conduct was, if ethically questionable, within the bounds prescribed by law.

Furthermore, the court agrees with Defendants that Plaintiffs have not shown that the federal regulation they cite in support of their right to informed consent creates a liberty interest enforceable either under 42 U.S.C. § 1983 or by private right of action. The regulation at issue is 45 C.F.R. § 46.116. Plaintiffs have not provided any evidence of legislative intent to support such a notion. *Hodgson v. Mississippi Dept. of Corrections,* 963 F.Supp. 776, 791 (E.D. Wis. 1997). Neither have Plaintiffs cited any case law holding to that effect. Thus, Plaintiffs have not met their burden with respect to showing that the conduct complained of violated a clearly established federal statutory right.

Finally, with regard to any liability of Dr. Arsonson, the court notes that Plaintiffs do not specifically address that in their briefs. In any event, for the reasons set forth in its earlier decision, the court denies Plaintiffs' motion to reconsider as to Dr. Aronson.

CONCLUSION

For all the above reasons, the court DENIES Plaintiffs' motion to reconsider and AFFIRMS its earlier decision in its entirety.

IT IS SO ORDERED.

BY THE COURT:

/s/ Robert A. DeChambeau
The Honorable
Robert A. DeChambeau
Dane County Circuit Court
– Branch 1

April 6, 2001

STATE OF WISCONSIN	CIRCUIT COURT Branch 1	DANE COUNTY

LINDA A. ANDE,
CHARLES ANDE,
C.E.A. (a minor), and
C.L.A. (a minor),

Plaintiffs,

vs.

MEMORANDUM DECISION AND ORDER
Case No. 98 CV 1634

MICHAEL ROCK, et al.,

Defendants.

MOTIONS FOR SUMMARY JUDGMENT

This matter is before the court on the State Defendants' motion for summary judgment as well as on the Plaintiffs' motion for partial summary judgment against the State Defendants. For the reasons set forth herein, the court must GRANT the State Defendants' motion and DENY Plaintiffs'.

BACKGROUND

The facts in this case are not in dispute. In early 1985, researchers in the Department of Pediatrics at the University of Wisconsin School of Medicine (UWSM) instituted a study called the "CF Neonatal Screening Project," (CFNSP). Their objective was to test the efficacy of a presymptomatic treatment program for infants with cystic fibrosis (CF). The researchers believed that early treatment

of the disease could delay its onset and progression and reduce its severity. If their hypothesis proved true, the researchers hoped to see the addition of CF to the panel of other metabolic disorders already screened for in all newborns as required in Wisconsin.

The then existing newborn screening program did not include a test for CF. Up until the time of the CFNSP, diagnosis of CF did not generally occur until a child presented with symptoms such as ongoing lung, digestive and growth problems. The diagnosis was confirmed by a "sweat test." The average age of diagnosis was four (4) years. However, a recently developed and inexpensive bood test rendered feasible the mass screening of newborns for CF. The UWSM researchers planned to use the new screening test in their study.

Scientific and funding considerations required the use of a traditional research approach, i.e., randomly placing subjects into one of two groups, one experimental and the other a comparison or control group. The UWSM researchers thus proposed and implemented a plan whereby all newborns would be screened for CF and alternately placed in either the research group or the control group. Of the newborns placed in the research group, those testing positive for CF would receive the treatment regimen and their progress tracked.

By design, the results of the CF screen for newborns in the control group would not be revealed to either the parents or the child's doctor. Such an arrangement is known as a double blind control group. The researchers believed that that was the only way to achieve truly reliable research data. They believed that most parents informed of their child's positive CF test would elect early

treatment notwithstanding its experimental nature and potential risks. Thus, the newborns in the control group testing positive for CF would not receive treatment and would be left to come to diagnosis via the customary route. After four years, if such a child had not been diagnosed, the researchers would reveal the child's positive test results in a process known as unblinding the control group.

The CF test would be performed on blood samples taken for the already existing newborn screening program. Thus, there would be no extra procedures involved for any infant in the study. Parents were to be informed of the study through a brochure distributed to them by hospitals and birthing assistants at the birth of their child. The brochure contained information about the existing newborn screening program and added information about the CFNSP at the end. The brochure also contained a contact number for parents with questions or for those desiring the results of their child's CF test.

The principal researchers for the CFNSP were Philip M. Farrell and Norman Fost. In an article written for a professional research journal in 1989, Drs. Farrell and Fost acknowledged some ethical concerns inherent in the design of the CFNSP. First, they realized that infants testing positively for CF but placed in the control group would not receive treatment that could potentially benefit them. However, because the proposed treatment had not been proven effective yet, the researchers concluded that study participants in the control group would not be denied anything of known value. In addition, there were risks associated with the treatment as well.

Second, the doctors foresaw the possibility that a family whose child tested positive for CF but was placed in the control group might conceive another child prior to the first child's CF diagnosis. The doctors believed that in some but not all such cases, the family would have chosen not to conceive rather than risk having a second child with CF. However, the doctors considered such a scenario remote enough that the potential positives to come out of the project far outweighed that risk.

The project began in 1985, with the last CF screening as part of the study occurring in April, 1994. By October, 1993, the researchers were confident enough in the project's results to suggest to the Newborn Screening Advisory Panel that the CF test should be added to the list of tests already routinely performed. In January, 1995, the Wisconsin Department of Health and Social Services issued an emergency order to that effect. The emergency order was replaced by permanent order in August, 1995.

Plaintiffs Linda and Charles Ande's first child, C.E.A., also a plaintiff in this action, was born on July 13, 1993. C.E.A.'s CF screen was positive. However, C.E.A. was randomly placed in the control group so the test results were not revealed to either her parents or her doctor. Before C.E.A. reached the age to two, she had presented with symptoms such that her doctor suspected C.E.A. had CF. In late June, 1995, a sweat test confirmed that diagnosis. A few days later, the Andes were informed that C.E.A. had previously been screened for CF as part of the CFNSP, that she had tested positive, and that she had been placed in the blinded control group.

On or about June 30, 1995, the Andes learned they were pregnant with their second child, C.L.A., also a plaintiff in

this action. the date of conception was determined to have been on or about June 7, 1995. In September, 1995, prenatal testing revealed that C.L.A. also had CF.

The Andes now charge that had they known of C.E.A.'s diagnosis prior to C.L.A.'s conception, they would have taken precautions not to conceive a second time, rather than risk having a second child with CF. The Andes further charge that the UWSM researchers failed to obtain their informed consent for C.E.A.'s participation in the study. They complain that not knowing of C.E.A.'s positive CF screen effectively denied their firstborn the proper care and treatment for her condition, resulting in their emotional pain and suffering, loss of enjoyment of life, loss of family companionship, loss of consortium, and economic damages.

Because those in charge of and administering the CFNSP were state employees, on December 15, 1995, the Andes filed a notice of claim pursuant to Wis. Stat. § 893.82. The Andes filed an amended notice of claim on November 18, 1997. This action was subsequently filed on June 23, 1998.

STANDARD OF REVIEW

The purpose of summary judgment is to avoid trial when ther [sic] are no issues to be tried. *See* Wis. Stat. § 802.08(2). *See also Transportation Ins. Co. v. Hunzinger Const. Co.*, 179 Wis. 2d 281, 289-90, 507 N.W.2d 136 (Ct. App. 1993). Summary judgment is appropriate when the pleadings, depositions, affidavits and other papers on file show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *See* Wis. Stat. § 802.08(2). It is a judgment

rendered on the merits of the case without a trial. *See Truesdill v. Roach*, 11 Wis. 2d 492, 499, 105 N.W.2d 871 (1960).

In considering a motion for summary judgment, the court should first examine the complaint to determine whether it states a claim, then review the answer to determine whether it presents a material issue of fact or law. *See Brownelli v. McCaughtry*, 182 Wis. 2d 367, 372, 514 N.W.2d 48 (Ct. App. 1994). If the court determines that the complaint and answer are sufficient, the court next examines the moving party's affidavits and other supporting papers to determine whether they establish a prima facie case for summary judgment. *See id.* If they do, the court then looks to the opposing party's affidavits and supporting papers to determine whether there are material facts in dispute which entitle the opposing party to a trial. *See id.*, at 372-73.

However, factual disputes must be genuine, and material to the issues in the case. *See Baxter v. DNR*, 165 Wis. 2d 298, 312, 477 N.W.2d 648 (Ct. App. 1991). The "mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *See id.* A factual dispute is genuine if the "evidence is such that a reasonable jury could return a verdict for the nonmoving party." *See id.*

Any doubt as to the existence of a genuine issue of material fact should be resolved against the moving party. *See Park Bancorporation, Inc. v. Slettleland*, 182 Wis. 2d 131, 141, 513 N.W.2d 609, *rev. denied*, 520 N.W.2d 88 (Ct. App. 1994). The burden is on the moving party to establish

the absence of a factual dispute and entitlement to judgment as a matter of law. *See id.*

DECISION

In their complaint, Plaintiffs allege eight causes of action, one of which they have since conceded should be dismissed. The court agrees and hereby dismisses Plaintiffs' strict liability claim against the State Defendants. Of the remaining seven allegations, the court will address each in turn.

I. NEGLIGENCE – MEDICAL MALPRACTICE

Plaintiffs charge that Defendants were negligent in failing to obtain Linda and Charles A Ande's informed consent for C.E.A. to participate in the CFNSP. Plaintiffs Linda and Charles Ande further charge Defendants were negligent for their failure to timely disclose C.E.A.'s CF screening results and thus to timely diagnose C.E.A.'s cystic fibrosis. The Andes claim that this negligence resulted in the wrongful birth of their daughter C.L.A. The Andes further claim that this negligence has caused physical injury, pain and suffering, loss of consortium, loss of family companionship, loss of enjoyment of life, and other economic and emotional injuries to both of their daughters. Finally, Linda and Charles Ande claim that they have suffered all of the identical injuries with the exception of physical.

The State Defendants counter that as C.E.A.'s CF screening was part of a research project, it cannot constitute medical malpractice. Defendants claim that since there was no medical malpractice, any other [sic] other state claim based on Plaintiffs' allegations is barred for

Plaintiffs' failure to timely comply with the notice of claim requirements of Wis. Stat. § 893.82. Additionally, Defendants assert that any duty to inform there may have been would have lain with the Department of Health and Social Services (DHSS) pursuant to Wis. Admin Code § HSS 115.05(2), or alternatively, with the State Laboratory of Hygiene which performed the CF test.

The court agrees with the State Defendants that there was no medical malpractice in this case. The researchers involved with the CFNSP were not doctors to any of the plaintiffs. Plaintiffs themselves admit that the investigators did not reveal the CF screen results of those study participants in the control group to either a child's parents of [sic] doctors. Thus, no doctor-patient relationship existed between any of the Andes and the people involved in the CFNSP. This court's interpretation of the law of medical malpractice is that a doctor-patient relationship is a fundamental element, *see Mathias v. St. Catherine's Hospital, Inc.*, 212 Wis. 2d 540, 550, 569 N.W.2d 330 (Ct. App. 1997) (quoting *Kelly v. Methodist Hosp.*, 664 A.2d 148, 151 (Pa. Super. Ct. 1995)), and that without it, medical malpractice does not lie.

II. NEGLIGENT MISREPRESENTATION

Plaintiffs allege that Defendants had a duty to provide Plaintiffs with information as to all aspects of C.E.A.'s participation in the CFNSP. Plaintiffs further allege that Defendants' failure to do so, as well as Defendants' failure to obtain the Andes' consent for C.E.A.'s enrollment in the study and Defendants' failure to timely inform the Andes that C.E.A. had cystic fibrosis constitutes negligent misrepresentation on Defendants' part.

Plaintiffs claim that their reliance on Defendants' misrepresentations caused physical injuries to C.E.A. and C.L.A. Plaintiffs further claim that Defendants' misrepresentations caused all the Plaintiffs to endure emotional pain and suffering, loss of consortium, loss of enjoyment of life, loss of family companionship, and economic damages. Finally, the Andes claim that Defendants' misrepresentations resulted in the wrongful birth of C.L.A.

The State Defendants assert that Plaintiffs failed to strictly comply with the notice of claim requirements of Wis. Stat. § 893.82. Defendants state that "[i]t is clear from the second amended complaint at 4-6, paras. 16-32, that the 'event causing the injury . . . giving rise to the civil action. . . . ,' Wis. Stat. § 893.82(3), was the fact that Linda and Charles Ande were not informed prior to the conception of C.L.A. on June 7, 1995, that C.E.A. had tested positive for cystic fibrosis." Defendants state that, pursuant to Wis. Stat. § 893.82(3), Plaintiffs had 120 days from June 7, 1995 in which to file their notice of claim against the State Defendants and that failure to do so bars all state claims other than medical malpractice, for which the period of limitations is 180 days.

Defendants have provided a copy of the two notices of claim filed by the Andes. The first one was filed no earlier than December 15, 1995. Even if the date their cause of action accrued is deemed to be on or about June 26, 1995, the day the Andes learned of C.E.A.'s positive CF screening at birth, Plaintiffs should have filed notice of claim by October 24, 1995. The first notice of claim clearly was filed outside the required 120 days. The Andes' amended notice of claim was not filed until at least November 18, 1997, so far outside the required time period that there is no reason for the court to consider it.

There is ample Wisconsin case law interpreting Wis. Stat. § 893.82 mandating strict compliance with the statute. *See Kellner v. Christian*, 197 Wis. 2d 183, 195, 539 N.W.2d 685 (1995); *Modica v. Verhulst*, 195 Wis. 2d 633, 641-42, 536 N.W.2d 466 (Ct. App. 1995). *See also Riccitelli v. Broekhuizen*, 227 Wis. 2d 100, 116, 595 N.W.2d 392 (1999) (quoting *Oney v. Schrauth*, 197 Wis. 2d 891, 904, 541 N.W.2d 228 (Ct. App. 1995). Failure to comply with Wis. Stat. § 893.82 precludes the court's jurisdiction over any of Plaintiffs' claims to which it applies. Thus Plaintiffs' claim of negligent misrepresentation against the State Defendants is barred for Plaintiffs' failure to comply with Wis. Stat. § 893.82.

III. FRAUDULENT REPRESENTATION

The same law and principles applicable to Plaintiffs' claim of negligent misrepresentation also apply to this claim. Thus, the court finds that the claim of fraudulent representation is also barred as against the State Defendants for Plaintiffs' failure to comply strictly with the requirements for notice of claim, under Wis. Stat. § 893.82.

IV. CONSPIRACY TO COMMIT FRAUD

Plaintiffs complain that by making the fraudulent representations alleged in the previous cause of action, the State Defendants conspired to commit fraud against Plaintiffs. Plaintiffs claim that in so doing, the State Defendants violated both Wisconsin common law and 42 U.S.C. 1985. Plaintiffs claim that this conspiracy caused physical injuries to C.E.A. and C.L.A. Plaintiffs further claim that this conspiracy caused all the plaintiffs to endure emotional pain and suffering, loss of consortium,

loss of family companionship, loss of enjoyment of life, and other economic and emotional injuries. Finally, Plaintiffs claim that this conspiracy resulted in the wrongful birth of C.L.A.

As to a state claim of conspiracy to commit fraud, the State Defendants assert Plaintiffs' failure to comply with Wis. Stat. § 893.82. As to a federal claim of conspiracy to commit fraud under 42 U.S.C. § 1985, the State Defendants assert that they are entitled to qualified immunity.

42 U.S.C. § 1985 was promulgated in the nineteenth century primarily for the purpose of combatting groups of White Americans conspiring to interfere with the rights under the Thirteenth, Fourteenth, and Fifteenth amendments of Black Americans and their allies. Under the general title of "Conspiracy to interfere with civil rights," the section has three subsections: (1) Preventing officer from performing duties; (2) Obstructing justice; intimidating party, witness, or juror; and (3) Depriving persons of rights or privileges.

Plaintiffs do not specify which subsection of 42 U.S.C. § 1985 they accuse Defendants of violating. Likewise, they do not discuss any common law on the subject. Nor do they provide the court with any case law authority upon which to base this claim. Plaintiffs have not provided any evidence to support a claim that their civil rights have been violated. Thus, the court, by virtue of its inherent powers, dismisses Plaintiffs claim that Defendants conspired to commit fraud either in violation of Wisconsin common law or in violation of 42 U.S.C. § 1985.

V. VIOLATION OF 42 U.S.C. SEC. 1983 – DENIAL OF DUE PROCESS

Plaintiffs allege that by failing to obtain the Andes' informed consent to C.E.A.'s enrollment in the CFNSP, and failing to disclose the results of C.E.A.'s CF screening prior to the conception of C.L.A., the State Defendants violated their right to substantive due process under the Fourteenth Amendment to the United States Constitution. The particular due process right Plaintiffs allege were denied were [sic] Linda and Charles Andes' property right to information about C.E.A.'s medical condition. C.E.A.'s and C.L.A.'s respective liberty interests in maintaining their health and bodily integrity, and all the Plaintiffs' rights to privacy.

Plaintiffs claim that the State Defendants' violations caused C.E.A. and C.L.A. physical injuries. Plaintiffs further claim that these violations have caused all the Plaintiffs to endure emotional pain and suffering, loss of consortium, loss of family companionship, loss of enjoyment of life, and other economic and emotional injuries. Finally, Plaintiffs claim that these violations resulted in the wrongful birth of C.L.A.

The State Defendants assert a defense of qualified immunity. The Defendants contend that the fact that the research project received some of its funding from the federal government proves that the project must have been in compliance with governing federal regulations, 45 C.F.R. Part 46. In any event, Defendants urge that they reasonably believed their conduct was lawful based on the fact that the CFNSP received federal funds conditioned upon the project's compliance with federal regulations.

Government officials are shielded from damage liability for performing their discretionary functions to the extent that their conduct does not violate clearly established federal statutory or constitutional rights. *See Harlow v. Fitzgerald*, 457 U.S. 800, 817-18 (1982). For policy reasons, such immunity is favored. *See Baxter v. DNR*, 165 Wis. 2d 298, 302, 477 N.W.2d 648 (Ct. App. 1991) (quoting *Melton v. City of Oklahoma City*, 879 F.2d 706, 728-29 (10th Cir. 1989).

In order to decide whether the defense of qualified immunity applies, the court must first determine the constitutional right Plaintiffs complain was violated. *See County of Sacramento v. Lewis*, 118 S.Ct. 1708, 1715, n.5 (1998). The right must be alleged with particularity. *See Anderson v. Creighton*, 483 U.S. 635, 640 (1987). Then, the court must determine whether that right was a clearly established constitutional right, such that a reasonable public official would have notice that his or her actions violated it. *See Burkes v. Klauser*, 185 Wis. 2d 309, 339, 517 N.W.2d 503 (1994), *cert. denied*, 115 S.Ct. 1102 (1995).

For the defense of qualified immunity to fail, the plaintiff must show a "sufficient consensus" of all relevant case law indicating that the official's conduct was unlawful. *See Landstrom v. Illinois Dept. of Children*, 892 F.2d 670, 676 (7th Cir. 1990). Plaintiff must cite more than one closely analogous case "decided prior to the defendants' challenged actions." *See Upton v. Thompson*, 930 F.2d 1209, 1212 (7th Cir. 1991) (quoting *Rakovich v. Wade*, 850 F.2d 1180, 1205 (7th Cir.), *cert. denied*, 488 U.S. 968 (1988).

Here Plaintiffs allege primarily a denial of their rights to informed consent, both for Linda and Charles Ande to

consent to C.E.A.'s participation in the CFNSP, and for C.E.A., through her parents, to consent to participate. Plaintiffs' strongest support comes from the federal regulation itself, which states in relevant part:

> Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

45 C.F.R. § 46.116. However, the law of qualified immunity strongly suggests that merely pointing to a federal regulation is not sufficient to overcome that defense. As noted above, Plaintiffs must cite more than one "closely analogous case" establishing that Defendants have violated a clearly established constitutional right. There must be a consensus of all the relevant case law on the issue. The Plaintiffs here have simply not met that burden.

Every case Plaintiffs cite on the issue of informed consent deals with humans having been subjected to unwanted, but *affirmative*, medical procedures or treatments. In the court's opinion, there is a clear distinction between the cases cited by Plaintiffs and the case at bar. Here, Defendants were not subjecting study participants to an invasive procedure in the initial CF screening. Infants' blood samples were routinely taken for the purpose of screening for several other congenital diseases. The CFNSP, at no expense to study participants, merely added the CF screen to [sic] panel of diseases already tested for.

Moreover, the only actual treatment dispensed in the study was to the participants whose CF screen results were positive. In those cases, the study's design called for

a child's results being reported to its doctor and in turn being reported to its parents in order to obtain the parents' consent for their child to receive an experimental treatment which carried some risks, but which also carried the potential for substantial benefits to the child. In the cases cited by Plaintiffs on the right to informed consent, the experiments in question did not hold the possibility of benefits to their subjects, rather they were for the edification of the researchers performing the experiments.

Finally, the court finds that the State Defendants' reliance on the institutional review board's (IRB) approval of the Defendants' obtaining implied consent was reasonable. Although hospitals and birthing centers were strongly encouraged by DHSS to distribute the Neonatal Screening Program brochures to new parents, and to obtain parents' signatures on the acknowledgement and refusal forms that were to accompany the brochures. The May, 1990 Newborn Screening Newsletter, put out by the State Laboratory of Hygiene, summarized the use of those materials and the status of parental knowledge of newborn screening for the previous four years. The newsletter made it clear that although DHSS rules required informed consent for all newborn screening, several surveys reported varying levels of parental awareness or the lack thereof. Thus, although strict compliance with the regulation was encouraged, it appears not to have been enforced.

VI. PUNITIVE DAMAGES

As Plaintiffs' federal claims fail due to the State Defendants' qualified immunity, Plaintiffs are not entitled to any punitive damages related to those claims. Additionally, with

respect to any state claims, no punitive damages are allowed or recoverable under Wis. Stat. § 893.82(6).

VII. INJUNCTIVE RELIEF

Plaintiffs cite no authority for their claim of injunctive relief. Neither do they address this claim in either of their briefs. The court finds no reason to grant injunctive relief to Plaintiffs in this case.

VIII. LIABILITY OF DR. RICHARD ARONSON

Plaintiffs charge that as Chief Medical Officer for Family And Community Health for the Division of Public Health within DHSS, Dr. Aronson had a duty to inform the Andes of C.E.A.'s positive CF screening as soon as he became convinced that the experimental treatment of the CFNSP was substantially beneficial. Plaintiffs further charge that Dr. Aronson had a responsibility to ensure that parents were fully informed of the newborn screening program and the CFNSP in particular.

Aronson asserts that he had no duty to inform the Andes of C.E.A.'s positive CF screening. Aronson further asserts that he is immune from suit under Wis. Stat. § 893.80 and Wisconsin's common law doctrine of governmental immunity for state employees in the performance of their discretionary functions.

The court agrees that Aronson is immune from suit under Wisconsin's governmental immunity doctrine. *See Kimps v. Hill*, 200 Wis. 2d 1, 9-11, 546 N.W.2d 151 (1996). Plaintiffs allege that Aronson's immunity defense fails because his conduct falls within at least one of three exceptions to the immunity rule. *See generally, Kierstyn v.*

Racine Unified School District, 228 Wis. 2d 81, 596 N.W.2d 417 (1999). However, the court is not persuaded by any of Plaintiffs' arguments to that effect.

First, Plaintiffs argue that Aronson's [sic] had a ministerial duty to inform the Andes of C.E.A.'s positive CF screening. Plaintiffs alleges that Aronson's duty was compelled by federal rule 45 C.F.R. sec. 46.116(b)(5), and Wis. Stat. §§ 48.981(2) and (3), and 253.13(2) and (5). However, the court agrees that none of these statutes imposed a duty upon Aronson to inform the Andes of C.E.A.'s result. 45 C.F.R. sec. 46.116 imposes its requirements upon a research project investigator, which clearly does not apply to Aronson.

Further, Wis. Stat. § 48.981(2) imposes a duty to report child abuse or neglect on any party personally involved with the subject child. As Aronson had no personal relationship of any kind with C.E.A. or the Andes, this statute clearly does not contemplate Aronson's function. For the same reason, Wis. Stat. § 48.981(3) also does not apply to Aronson.

Finally, Wis. Stat. §§ 253.13(2) and (5) did not require Aronson to inform the Andes of C.E.A.'s positive CF screening. Those sections regard required tests for congenital disorders of newborns. However, at the time C.E.A. was born in 1993, the test for CF was not yet required. In any event, these statutes did not impose a duty upon Aronson personally to inform the Andes of C.E.A.'s newborn screening results.

Next, Plaintiffs argue that Aronson's conduct falls within the "known danger" exception to immunity. *See Kierstyn*, 228 Wis. 2d at 95. However, the court is not persuaded by this argument either. Although the positive

results of the CFNSP appeared to be steadily increasing at the time C.E.A. was born, the experiment was still active and ongoing. Regardless of Plaintiffs' assertions to the contrary, the new treatment was not yet the standard of care. Thus, there was no new "known danger" in allowing control group study participants to come to diagnosis in the traditional way.

Third and finally, Plaintiffs charge that Aronson's conduct falls under the "professional discretion" exception. *See Kierstyn*, 228 Wis. 2d at 97. Plaintiffs cite *Kierstyn* to support this allegation. However, the reasoning set forth in *Kierstyn* is inapplicable here. In *Kierstyn*, the court discusses its use of this exception in prior cases, both occurring in medical contexts. *See id.* However, the medical cases discussed in *Kierstyn* involved doctor-patient relationships, which is absent in the present case between Aronson and any of the Andes. Thus, the court deems the cases discussed in *Kierstyn* insufficiently analogous to find applicable the "professional discretion" exception to immunity here.

CONCLUSION

For the reasons stated herein, the court GRANTS summary judgment to the State Defendants on all claims, other than strict responsibility, which has been dissmissed [sic] by stipulation of the parties, and conspiracy to commit fraud in violation of 42 U.S.C. § 1985, which the court dismisses sua sponte. The court GRANTS summary judgment to Defendant Richard Aronson because it finds that Aronson is immune from suit under Wisconsin's common law doctrine of governmental immunity. Accordingly,

the court DENIES Plaintiffs' motions for partial summary judgment.

IT IS SO ORDERED.

Dated this 11 day of January, 2001.

BY THE COURT:

/s/ Robert A. DeChambeau
Honorable Robert A. DeChambeau
Dane County Circuit Court –
Branch 9

[SEAL]

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You are hereby notified that the Court has entered the following order:

01-1009 *Ande et al. v. Rock et al.*

A petition for review pursuant to Wis. Stat. § 808-10 having been filed on behalf of plaintiffs-appellants-petitioners, Linda A. Ande, Charles Ande, C.E.A., a minor, and C.L.A., a minor, and considered by this court;

IT IS ORDERED that the petition for review is denied, without costs.

Sykes, J., did not participate

Cornelia G. Clark
Clerk of Supreme Court

[SEAL]

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You are hereby notified that the Court has entered the following **AMENDED** order:

01-1009 *Ande et al. v. Rock et al.*

A petition for review pursuant to Wis. Stat. § 808-10 having been filed on behalf of plaintiffs-appellants-petitioners, Linda A. Ande, Charles Ande, C.E.A., a minor, and C.L.A., a minor, and considered by this court;

IT IS ORDERED that the petition for review is denied, without costs.

Abrahamson, C.J., did not participate

Cornelia G. Clark
Clerk of Supreme Court

Supreme Court, U.S.
FILED
NOV 21 2002
CLERK

No. 02-640

In The

Supreme Court of the United States

LINDA A. ANDE, CHARLES ANDE,
and C.E.A., Their Minor Child,

Petitioners,

v.

NORMAN C. FOST, PHILIP M. FARRELL,
ELAINE H. MISCHLER, and ANITA LAXOVA,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE SUPREME COURT OF WISCONSIN

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a decision by this court is needed to clarify that when an individual is not in a custodial setting in which the State has limited her ability to care for herself and the State did not place the individual in a position of danger she would not otherwise have faced, the State has no constitutional duty to provide substantive services to her.

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No. 02-640

In The

Supreme Court of the United States

LINDA A. ANDE, CHARLES ANDE, and C.E.A., Their Minor Child,

Petitioners,

v.

NORMAN C. FOST, PHILIP M. FARRELL, ELAINE H. MISCHLER, and ANITA LAXOVA,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE SUPREME COURT OF WISCONSIN

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

ARGUMENT FOR DENYING THE PETITION

I. THE PETITION SHOULD BE DENIED BECAUSE C.E.A. WAS NOT IN A CUSTODIAL SETTING IN WHICH THE STATE LIMITED HER ABILITY TO CARE FOR HERSELF AND THE STATE DID NOT PLACE HER IN A POSITION OF DANGER SHE WOULD NOT OTHERWISE HAVE FACED.

Notwithstanding the argument of the petitioners ("Andes") to the contrary, both the Dane County Circuit Court and the Wisconsin Court of Appeals reached the correct result in what is a relatively simple and straightforward case based on well-established legal precedent.

The Andes' claim under 42 U.S.C. § 1983 is that respondents Fost, Farrell, Mischler, and Laxova ("State") violated their *substantive* due process rights under the Fourteenth Amendment by placing C.E.A. in the control group as part of the cystic fibrosis ("CF") study. However, placing C.E.A. in the control group meant only that she would be treated no differently than if there had been no study (petition, App. 22). Indeed, the Andes didn't even know C.E.A. was in the control group until late June, 1995, when, at almost two years of age, a "sweat test" performed as part of ordinary medical care confirmed that she had CF (petition, App. 30).

Hence, the Ande's entire argument is based on the assumption that the State had a duty under the substantive due process clause of the Fourteenth Amendment to take some affirmative action to see that the Andes were informed

that C.E.A. tested positive for CF much earlier, at birth, although it was not standard medical practice to do so, and that she was offered pre-symptomatic treatment. Moreover, to have provided the additional service would have impaired the integrity of the study. (In addition, the Andes argue that the State was required by substantive due process to obtain their informed consent before placing C.E.A. in the control group even though there was no medical treatment to which informed consent could have been given).

However, the substantive due process clause imposes a duty on the State to assume some responsibility for the general well being of a person only if the State takes the person into custody. *DeShaney v. Winnebago Soc. Serv.*, 489 U.S. 189 (1989) and cases cited therein; "The State's duty to protect does not arise from the State's knowledge of the person's problems, 'but from the limitation which [the state] has imposed on [the individual's] freedom to act on his own behalf.'" *Dykema v. Skoumal*, 261 F.3d 701, 705 (7th Cir. 2001) (quoting *DeShaney*, 489 U.S. at 200). See also *Reed v. Gardner*, 986 F.2d 1122, 1125 (7th Cir. 1993) (quoting *Gregory v. City of Rogers*, 974 F.2d 1006, 1010 (8th Cir. 1992) (en banc) "'([T]he Due Process Clause imposes a duty on state actors to protect or care for citizens in two situations: first, in custodial and other settings in which the State has limited the individuals' ability to care for themselves; and second, when the State affirmatively places a particular individual in a position of danger the individual would not otherwise have faced.)'(citations omitted);" *Archie v. City of Racine*, 847 F.2d 1211, 1223 (7th Cir. 1988) (en banc), *cert. denied*, 489 U.S. 1065 (no § 1983 liability for failure to provide requested emergency services: "The state did not cause DeLacy's diseases or otherwise propel her into danger .... It did not take DeLacy into custody. It did not hinder her from seeking other sources of

aid.... It therefore did not violate her rights under the Due Process Clause").

Here, the undisputed facts establish that C.E.A. was not in a custodial or other setting in which the State limited her ability to care for herself and that the State did not affirmatively place her in a position of danger she would not otherwise have faced: The State did not cause C.E.A.'s CF; it did not prevent her from seeking medical care; nor have the Andes presented any evidence that C.E.A. would have been tested for CF if there had been no CF study. In sum, the actions of the State placed the Andes in no worse position than they would have been had there been no study.

> The Due Process Clause
>
> forbids the State itself to deprive individuals of life, liberty, or property without "due process of law," but its language cannot fairly be extended to impose an affirmative obligation on the State to ensure that those interests do not come to harm through other means. Nor does history support such an expansive reading of the constitutional text.

DeShaney, 489 U.S. at 196.

What the Andes are proposing is an expansion of the concept of substantive due process that would have required the State to take affirmative action to protect the Andes by providing them with pre-symptomatic diagnosis of and treatment for C.E.A.'s CF. This position leaves virtually no limits on an expanding concept of substantive due process. Further, an expansion would be contrary to *DeShaney* and ignore this Court's own "'reluct[ance] to expand the concept of substantive due process because guideposts for

responsible decision-making in this uncharted area are scarce and open-ended.'" *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997) (quoting Collins v. Harker Heights, 503 U.S. 115, 125 (1992).

In addition, any such expansion would, in any event, clearly entitle the State to qualified immunity since it would represent an unprecedented change in substantive due process law.

II. THE PETITION SHOULD BE DENIED BECAUSE THE STATE HAD NO CONSTITUTIONAL DUTY TO FUND COMPLETION OF THE TESTING ON C.E.A.'S BLOOD SAMPLE TO DETERMINE WHETHER SHE TESTED POSITIVE FOR CF.

The Andes' qualified immunity argument is internally inconsistent. On the one hand, they argue that the general statement of the law with respect to the right to bodily integrity applied "with obvious clarity" to the State's conduct (petition at 19). On the other hand, the Andes argue that there is a "desperate need" (petition at 14) for this Court "to clearly delineate" (petition at 17) the applicability of this general statement to the State's conduct.

The Andes assert that "the unlawfulness of such conduct can surely be inferred from the existing line of cases which makes it unlawful to subject humans to invasive medical experimentation without their consent" (petition at 14) and that "The conduct at issue in this case is so egregious, and so stunning, that there need not be any factually similar case at all" (petition at 23). Yet, they concede that actions like the State's "are all acceptable practices in the field of human medical research" (petition at

16). In addition, the Dane County Circuit Court found that the CF study had "[National Institutes of Health] funding and the [Institutional Review Board's] ongoing approval" (petition at App. 24; footnotes omitted).

The fact is there are no analogous cases because it is clear that a State does not violate a person's substantive due process rights by virtue of the fact that the person is a member of a control group in a research study. For the control group is not treated any differently than the general public, or, as the Dane County Circuit Court put it, the result of the CF study on the control group was "not doing anything other than what has always been done which in this case amounted to leaving them alone" (petition, App. 22). The State did not know that C.E.A. had CF. The Andes would require the State to ensure that a person's interest in bodily integrity does not come to harm by means of which the State might not even be aware.

Indeed, in the CF study, the testing on the blood of those children in the control group was not even completed until they either reached four years of age (petition, App. 5 n. 3) or, as in the case of C.E.A., when the children were diagnosed with CF by the traditional "sweat test" (petition, App. 28). Consequently, the State was not even aware that C.E.A. had tested positive for CF until after she was diagnosed with CF using the "sweat test" (petition, App. 30). For it was only after the "sweat test" confirmed the diagnosis (*ibid)* that, in accordance with the design of the study (petition, Ap. 5 n.3), the testing on C.E.A.'s blood sample was completed and showed that she had CF. In other words, the Andes knew before the State did.

Therefore, the Andes' argument is really that the State violated their substantive due process rights by not completing the testing on C.E.A.'s blood sample as soon as it was taken and then informing them that C.E.A. had tested

positive. But the non-reporting is not invasive of the body. Moreover, unless the State has placed an individual in a custodial setting or has placed the individual in a position of danger in which the individual would not otherwise have been placed, the State has no constitutional duty to fund medical services or to provide any other substantive services to them. *DeShaney*, 489 U.S. at 196.

Consequently, contrary to what the Andes' claim, what cannot only be inferred from previous cases but is, in fact, abundantly clear from them, is that the State had no constitutional duty to test C.E.A.'s blood sample at all. And without such a duty, the State certainly could not have had a constitutional duty to inform the Andes of the results it didn't have because the testing had not been completed.

Under the Andes' argument, every time a State believes certain medical services would be beneficial to its citizens it would have a constitutional duty to expend money and other resources to provide those services or risk violating the substantive due process rights of its citizens. This Court has held to the contrary a number of times. *DeShaney*, 489 U.S. at 196.

If, as the Andes contend, "Qualified immunity was improperly granted" (petition at 17; emphasis omitted), it was not "because the lower courts' decisions conflict with this Court's decisions in *United States v. Lanier*, and *Hope v. Pelzer"*, (petition at 17, emphasis omitted), but because there was no constitutional violation at all. As this Court noted in *Hope v. Pelzer,* 536 U.S. ____, 122 S. Ct. ____, 153 L. Ed. 2 666, 676 (2002), "The threshold inquiry a court must undertake in a qualified immunity analysis is whether plaintiff's allegations, if true, establish a constitutional violation." Here, they do not, and, therefore, there was no need for the lower courts to even determine whether the State was entitled to qualified immunity.

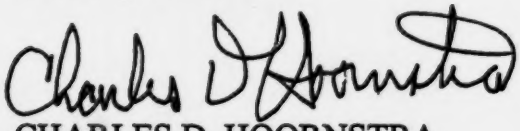
CONCLUSION

The petition for a writ of certiorari should be denied.

Dated at Madison, Wisconsin, this 14th day of November, 2002.

Respectfully submitted,

JAMES E. DOYLE
Attorney General



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